



PUBLIC MANAGEMENT

OCCASIONAL PAPERS

No. 18

CO-OPERATIVE APPROACHES TO REGULATION



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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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- to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
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Publié en français sous le titre :
RÈGLEMENTATION : STRATÉGIES DE COOPÉRATION

Reprinted 1998

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FOREWORD

Regulations are the sinews of modern government, the legal instruments that connect abstract government policies with the day-to-day activities of commerce and private life. In the highly-developed administrative states characteristic of OECD countries, government effectiveness has become to a significant degree dependent on the quality of the systems that develop, enforce, adjudicate, and terminate regulations. As an instrument of governance, regulations will continue to be used to meet a wide variety of legitimate social and economic needs.

In the past 20 years, few modern reforms of the public sector have received more attention, and stimulated more controversy, than has regulatory reform. Few governments are satisfied with the quality, effectiveness and cost of regulation. New demands – from opening world markets and international integration, from problems of unprecedented scale such as environmental degradation and high non-cyclical unemployment, and from emerging interest groups such as consumers, to mention only a few – have focused considerable attention on the role of regulation in causing and solving problems. There is growing evidence, for example, that reform of regulation, properly designed and carried out, can improve economic performance.

Today, regulatory reform has become a core element of modern, effective government. Today, almost all OECD countries have regulatory reform programmes, up from perhaps three or four in 1980, and more and more the debate focuses on how to reform rather than why reform is needed. This development can be compared to the adoption of modern fiscal budgeting agencies by governments earlier in this century to better control and manage national expenditures.

The new initiatives are aimed at improving the performance, impact, and institutions of regulation. These initiatives vary greatly in objective and design, but they have distinctive features that mark them as genuinely new management capacities enabling governments to regulate more carefully by answering key questions: Are regulatory costs justified by benefits? Does regulatory intervention produce more social and economic benefits than would alternatives? Are regulations designed to achieve policy objectives at lowest cost?

The work of the OECD Public Management Committee (PUMA) on regulatory management and reform attempts to respond to the specific needs of the new reform initiatives. The purpose is to provide better information – drawn from practical experience, comparisons, and international exchanges – on the benefits, costs, and risks of reform in the policies, management, processes and institutions of regulation.

The series of Occasional Papers on regulatory management and reform is intended to disseminate more widely the background papers, reports, and preliminary results prepared for the programme. The regulatory management and reform work and series of papers is led by Scott H. Jacobs of the Public Management Service. This report was prepared by Hans Huigen and technical assistance was provided by Jill Stobie and Marthe Wambaugh of the Public Management Service.

The papers are published on the responsibility of the Secretary-General of the OECD. The views expressed in the papers are those of the authors, and do not commit or necessarily reflect those of governments of OECD Member countries.

TABLE OF CONTENTS

Executive Summary	7
Introduction, by Hans Huigen	9
Chapter 1. Responsible Care® Initiative: Canadian Chemical Producers' Association A case study from Canada	13
I. Problem to be solved	13
II. Description of the Alternative	14
III. Role of government in implementing the alternative	16
IV. Experiences and assessment	16
V. Lessons learned	18
Chapter 2. The Advertising Standards Authority and the System of Self-Regulation in the United Kingdom, by Caroline Crawford	21
I. Problem to be solved	21
II. Description of the alternative	21
III. Role of government in implementing the alternative	24
IV. Experiences and assessment	25
V. Lessons learned	26
Chapter 3. The Covenant as an Instrument of Environmental Policy: A Case Study from The Netherlands, by Kees Bastmeijer	29
Introduction	29
Part I: The Development of the Environmental Covenant in the Netherlands	30
1. Categories of covenants	30
2. The rise of the covenant	31
3. Policy on covenants	32
4. Contents and procedure	32
5. The future	34
Part II: Case study on covenants with industry target groups	35
Introduction	35
I. Problem to be solved	35
II. Description of the alternative	35
III. Role of government in implementing the alternative	37
IV. Experiences and assessment	38
V. Lessons learned	39
Chapter 4. Flexibility Through Public Private Partnerships: Prevention and Harmonization in FDA's Seafood HACCP Regulatory alternative, by Daniel J. Chenok	41
I. Problem to be solved	41
II. Description of the alternative	43
III. Role of government in implementing the alternative	45
IV. Experiences and assessment	47
V. Lessons learned	49
Box	
1992 Code of Conduct for Environmental Covenants: A summary of Elements	33

EXECUTIVE SUMMARY

This Occasional Paper presents four case studies on alternatives to traditional regulation from Canada, the Netherlands, the United Kingdom and the United States. The case studies are developed as part of a larger activity on alternatives to traditional regulation under the work programme of the Public Management Committee of the OECD.

The case studies in this Occasional Paper are about ways in which governments and businesses are seeking to address economic and social problems by using new forms of co-operation that are different from traditional command-and-control regulation. A new kind of interaction between government and business is emerging in which both parties see the need for co-operative rather than adversarial relationships. In addition, there is increasing evidence that a co-operative approach to solving regulatory problems can lower costs for both parties and achieve equal or better performance in relation to policy objectives.

The case studies are organised according to a common framework designed to give information about the specific design and use of the alternative, positive and negative results, and more generally applicable lessons learned. Each case study is organised under five main headings:

- a description of the problem to be solved;
- description of the alternative, including design and operation;
- the role of government in implementing the alternative;
- experiences and assessment, covering issues like the effectiveness of the alternative, the costs and difficulties, and issues concerning legitimacy;
- summary of lessons learned, emphasizing those that may be of more general relevance.

The four alternatives presented here differ in their design and implementation, and indicate the wide range of possible co-operative approaches to regulation.

The case study from Canada examines a self-regulatory initiative: the chemical industry's "Responsible Care" initiative designed to protect employees, the community and the environment.

The case study from the United Kingdom also examines a form of self-regulation. The advertising industry in the United Kingdom has established its own set of principles, procedures, and sanctions, which are administered by the private Advertising Standards Authority with virtually no government involvement.

The case study from the Netherlands discusses "environmental covenants" developed in a framework of environmental law. The covenant is a type of contract negotiated between the government and a firm or a group of firms. Although adopted voluntarily, it has certain legal effects.

The case study from the United States discusses the implementation of a system of "process" regulation that shifts responsibility from the public to the private sector. The "HACCP" approach places clear responsibility for food safety with the firm, replacing an inspection based system which effectively required the regulatory authority to detect non-compliance.

These case studies, as well as others in the PUMA database suggest that, if designed and implemented properly, innovative alternatives such as those discussed in this Occasional Paper can stand alone or complement traditional regulation, increasing the range of tools available to governments to influence private behaviour to achieve public goals.

INTRODUCTION

by

by Hans Huigen*

Are there ways to improve the regulatory environment for businesses without losing sight of the need to effectively address economic and social problems? This is a key question today for both governments and businesses.

Governments have identified many reasons for reducing the use of traditional command-and-control regulation. Economic and social change appear to be occurring faster than governments can respond through command-and-control regulation. Rapid technological innovation in existing sectors and the emergence of new industries require that governments use more dynamic and flexible instruments in dealing with economic and social problems.

Responsiveness to innovation is important. Governments in many cases do not have the time to regulate in traditional ways. Product cycles, for example, are often much shorter than the time governments need to change regulation. Governments need new ways to balance the need for innovation in an international competitive environment, and the need to address social and economic problems.

At the same time governments face budget pressures. Traditional command-and-control regulation is often costly and time-consuming to develop and to keep up-to-date with the dynamic economic environment. Enforcement of command-and-control regulation is also costly for governments, and budgets for enforcement are not excluded from the overall pressures on government budgets.

Businesses also have reasons to co-operate with governments, partly because of negative experiences with command-and-control regulation, which can be costly to comply with and can interfere with the efficiency of business operations. Also, governments are not the only organisations today that are monitoring the behaviour of businesses. Interest groups, consumers and other businesses are also demanding more and more performance from businesses with regard to issues such as the environment and consumer information.

The case studies in this Occasional Paper are about ways in which governments and businesses are seeking to address economic and social problems by using instruments that are different from traditional command-and-control regulation. A new kind of interaction between government and business is emerging in which both parties see the need for co-operative rather than adversarial relationships.

The four case studies differ in their design and implementation and indicate the wide range of possible approaches falling under the heading "Co-operative Approaches to Regulation".

The Canadian case study on the Responsible Care initiative discusses how businesses in the chemical sector were very aware of the negative public image of their industry and that they needed to act to improve their environmental, health and safety record to avoid potentially very costly government controls. Leadership by a strong business association brought the industry together to create a system of codes on life cycle management that is intended to protect employees, the environment and communities affected by the operations of chemical producers. The case study shows that developing

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successful codes is a learning process that involves stakeholders, public information, staff training, and compliance verification procedures. Much time was spent on developing trust among competitors to bring out peer information and peer pressure and to create a strong mutual aid network among companies. Information sharing among peers, and mutual aid were an important underpinning for this initiative. The case study also shows that the incentives provided by this voluntary initiative can produce more environmental protection than required by regulation. Personal commitment, training, information-sharing among companies, and discussions with the public, plant communities, and governments can motivate executives and employees to focus on 'what is the right thing to do' in a way that legal mandates do not.

The Dutch case study on environmental covenants describes a situation in which both government and businesses felt there was a need to step away from an adversarial relationship towards a more co-operative relationship in which both parties have obligations. The government of course retains its obligation toward the public but in this case government was also willing to share obligations with industry. This brought about an atmosphere in which both sides, without losing sight of their primary responsibilities, could discuss problems much more openly and constructively. The obligations that the government has in these environmental covenants include informing the public about the covenants, giving credit for success to sectors or individual companies, co-ordinating better environmental licensing procedures, engaging in research together with industry, and informing the international community, especially EU countries and regulators, about the covenants. This latter obligation responds to fears on the side of Dutch industry that they might be confronted with two regulatory regimes that may not be in harmony and therefore costly to comply with. The covenants must be seen as part of a larger legal framework in the Netherlands dealing with the environment. Environmental goals are set in National Environmental Policy Plans (NEPP) that go through Parliament, and covenants are used as instruments for implementation of these plans.

In the United Kingdom case study on self-regulation in advertising, the advertising industry was aware that the confidence and trust of the audience (consumers) was essential to its product. Private standards alone were not enough to gain that trust. Independent oversight of the system of self-regulation was essential. The Advertising Standards Authority (ASA) was created as an independent body apart from both government and industry, that was funded by industry through a voluntary levy. The oversight system has proven to be effective. Apart from efforts to raise public awareness of the existence of the codes and of independent oversight, special attention is given to create incentives to comply with the codes. Several effective sanctions fitting the character of the industry are available to ASA. Government reviews have been helpful in making the industry realise that the system needs continuous improvement both in terms of the Codes and administration of the system.

The United States case study deals with seafood safety. Existing regulatory approaches based on command-and-control rules were not adequate to ensure seafood safety. Diminishing consumer confidence in seafood and pressure from trading partners led the U.S. Food and Drug Administration to adopt a new approach. In this case, a safety management system, developed in the private sector and known as Hazard Analysis Critical Control Points (HACCP) is made mandatory for all seafood processors. The case study demonstrates how working with industry can expand the capacity of government to achieve public goals in a more effective and efficient way. The system places the responsibility to identify and control problems with the individual firm, which allows for a varied and tailored approach compatible with-firm specific production processes to addressing risks rather than a one-size-fits all regulatory strategy. This has changed considerably the way the Food and Drug Administration enforces food safety; it must now work with the private sector to understand and address firm-specific risks.

There are significant differences between the types of instruments presented in these case studies and the transferability of these models to other areas or in other countries. One needs to have a good understanding of specific circumstances when designing effective instruments.

One of the questions frequently raised, especially with respect to the types of alternatives discussed in this Occasional Paper, is how to introduce such innovations into public administration. As in all cases, the process starts with recognition of a problem that exists or might occur in the near future. In the United States and Dutch case studies the problem arose from the interactions of existing regulation

and the new challenges facing both industry and governments. In the United Kingdom and Canada, businesses took the initiative from "enlightened self-interest", which gave them the opportunity to design a model that suited them. The role of government has in those cases been smaller. When business sets the agenda, it provokes governments to innovate. Once these institutions are established, governments need to deal with them when carrying out related policies.

Legitimacy issues also start to play a role. Part of the responsibility of governments is to ensure transparency, accountability and consultation with interested parties. These case studies show that such values can be served, but that they require continuing attention as the alternative is implemented. It is clear that transparency, accountability and consultation are not primary objectives of the private sector. The Canadian case study shows that business has not always been keen to be transparent and to open up consultation with interested parties. In a voluntary programme such as the Responsible Care initiative the issue of accountability is a difficult one. Why should a business be held accountable for the obligations that it took upon itself voluntarily and without government intervention? An attempt to answer that centres on the point that most likely the government would regulate differently (or even not regulate) when such a voluntary commitment on the side of industry has been made. Therefore, ensuring accountability when public interests are concerned should be a major concern in the design of a voluntary programme.

In all cases, building trust and confidence seems to be the starting point so that all parties are assured that risk of failure has been minimised. In the United States and Dutch case studies, where a regulatory approach already existed, trust had to be built within the government that a new approach could work. For the U.S. Food and Drug Administration the HACCP model will create considerable change in how it enforces food safety. Politicians, administrators, food safety inspectors and, ultimately, consumers need to trust this new system, which transfers a considerable amount of responsibility to the individual firm. In the Netherlands, development of the covenants involved Parliament. Since the Dutch covenants are voluntary, and businesses are engaging in a form of contract, trust in government needed to be built at the business level as well. In the United Kingdom and Canadian case studies, trust needed to be developed first within the business community to develop an instrument that itself was aimed at building trust with the public about business activities.

Both governments and businesses need in all cases to work on the issue of trust and continuously reinforce the trust of the public at large. How to do this depends on the specific circumstances of each case, but the case studies give much information on the kind of checks and balances needed to create an effective alternative to command-and-control regulation.

These case studies, as well as others in the PUMA database, suggest that, if designed and implemented properly, innovative alternatives such as those discussed in this Occasional Paper can stand alone or complement traditional regulation, increasing the range of tools available to governments to influence private behaviour to achieve public goals.

RESPONSIBLE CARE® INITIATIVE: CANADIAN CHEMICAL PRODUCERS' ASSOCIATION A CASE STUDY FROM CANADA*

I. PROBLEM TO BE SOLVED

This case study examines factors that led to the establishment of the Responsible Care initiative by Canada's chemical producers, and describes details of the programme. Were it not for this initiative, it seemed inevitable that governments would have been forced to legislate tougher measures to control the production and handling of chemicals in Canada and to deal with disaster avoidance and response scenarios. Governments in the 1970s and 1980s were operating, as was the chemical industry, in a climate of increasing public awareness and global concern about environmental issues, including sensational media and political coverage of ecological damage and emergencies involving chemicals.

Responsible Care is the name given by the Canadian Chemical Producers' Association (CCPA) to a programme that includes seven Guiding Principles and six Codes of Practice. The Responsible Care system is intended to help in protecting employees, the environment, and communities that are most directly affected by the operations of chemical producers. It formally commits members of the CPC "to achieve a standard of life cycle management of chemicals that meets the public's expectations of responsible environmental performance".

Beginning in the 1970s, the chemical industry in Canada took steps to present a positive profile to the Canadian public. It was perceived that, while the industry did not have a negative image, neither did it have a constituency that would be supportive if the chemical sector wished to lobby for particular public policies, or if problems arose. Some in the industry also reasoned that a more positive image would be good for employee morale, and might facilitate attraction of "the best and the brightest" to work for their companies. An early effort responding to industry concerns was the development of a set of guidelines for dealing with dangerous substances, and Responsible Care built on that beginning.

A catalyst for the alternative to regulation outlined in this study was the Bhopal, India disaster, which sent a shock wave through the chemical industry in Canada and elsewhere. Environmental activism also increased during the 1980s, partly as a result of publicity given to the possible effects of ozone depletion and global warming. There were also a few spills of chemicals being transported within Canada, incidents that caught the attention of the media and of the wider population.

The need to act preventively to reduce the risk of lawsuits was one lesson drawn from the aftermath of the Bhopal disaster. Because Canadians are less litigious than, for example, Americans, and because damage awards have traditionally been much lower in Canada, there is less likelihood of costly litigation against alleged polluters in Canada than there is in the United States. Nonetheless, Canadian judges sometimes borrow precedents from the United States (though they are not obliged to), and a lawsuit of any size could be embarrassing. It was prudent for the chemical sector to guard against large lawsuits, as public consciousness about environmental harms and related health issues increased.

* This paper has been adapted by the Secretariat from a paper prepared for the OECD by Allan McChesney. It has greatly benefited from the comments on an earlier version given by Jean Bélanger, former President of the Canadian Chemical Producers' Association.

Another strong catalyst for the development of the Responsible Care programme was the industry's desire to avoid becoming subject to stricter regulations by government. The imposition of detailed regulations was a real possibility, given the factors noted above. There was a concern that the U.S. approach of providing very detailed descriptions for every stage of processing might be adopted if the industry did not come up with its own alternatives.

Chemical producers and distributors in Canada were thus faced with a number of interrelated problems. There was a genuine fear of one day being responsible for damage to health if faulty production, distribution or transportation procedures were used. Aside from legal or ethical considerations, there was a general wish to ensure that the chemical industry attain a more positive image in the public eye. Industry planners were also aware that they would need to counteract an initial lack of public credibility when chemical company representatives attempted to provide a more environmentally friendly image.

II. DESCRIPTION OF THE ALTERNATIVE

In recent years the chemical industry has taken a number of initiatives to avoid difficulties with proposed or possible legislation. The most comprehensive attempt by the chemical sector to take charge of its own field of operations with respect to environmentally friendly management was the Responsible Care initiative. (No rival alternatives to traditional regulation were seriously considered during the initiative's development.)

Six Codes of Practice developed between 1986 and 1989 are part of the Responsible Care scheme. They define what is expected of a member company of the Canadian Chemical Producers' Association (CPC), the body that initiated the programme. The CPC was founded in 1962 and is an alliance of more than 60 chemical companies operating across Canada. The membership produces about 90 per cent of chemicals made in Canada. Total commitment to Responsible Care is now a condition of membership.

The Codes of Practice cover the following topics:

- community awareness and emergency response;
- research and development;
- manufacturing;
- transportation;
- distribution;
- hazardous waste management.

The Codes require member companies to implement specific procedures designed to protect employees, the community, and the environment.

Each Code of Practice includes criteria for evaluating progress. The Codes are supported by implementation manuals, seminars and workshops. In addition to providing information and guidance on proper protocol in normal circumstances, the Codes describe emergency procedures. These procedures are required to be field tested and updated on a regular basis.

The Codes call upon CPC members to meet or exceed the letter and spirit of all applicable laws at each stage of operation. If a member company's activities cannot be carried out in conformity with the applicable Code, the Code itself requires that the company not carry out that activity.

It should be made clear that the industrial areas covered by the CPC Responsible Care initiative deal almost entirely with products and services that are provided to other companies, rather than those involving direct relations with consumers.

Community Awareness and Emergency Response (CAER)

The CAER requirements are related to each of the other five Codes. An active CAER "right-to-know" programme must be in place at any site where chemicals are handled. Under CAER, each member company is required to:

- know community concerns and respond sensitively to them;
- advise the community of potential hazards associated with its operations;
- have its own emergency plan; and
- ensure that its emergency plan is integrated with any community emergency response plan.

Research and Development

The Research and Development Code covers all investigative technical work regarding new chemical products, processes, equipment and applications, as well as new uses for existing products. The Code covers each stage of development from initial research to marketing and beyond. No research may be performed by the company or through outside laboratories unless it conforms to the Code. No new product may be introduced unless it conforms to the Code.

Manufacturing

Both new and existing manufacturing sites are covered by this Code. It deals with all aspects of manufacturing and operations, including location of new plants and shutting down/decommissioning of existing plants. The Manufacturing Code requires that systems be initiated to protect employees, the community and the environment from any harmful effects of manufacturing operations. The design, construction, and operation of a plant are all relevant considerations.

Transportation

The Transportation Code requires that each member company transport chemicals and chemical products in a manner that minimises the risk of injury to the general population along transportation routes, and provides to people situated along those routes information concerning any dangers. Risk of injury must also be minimised for persons involved in transportation activities. Protection of the environment is an equal consideration. Member companies must have an active programme designed to improve performance continuously and to prevent accidents during all stages of transportation.

Distribution

The Distribution Code covers members' activities related to the sale of chemicals, chemical products and services, as well as the movement of goods that come from suppliers to be resold or to be converted into other products. The Code details standards, procedures, and guidance on related training for storage and handling of chemicals and chemical products. This sphere of chemical management is treated as overlapping with, but distinct from, transportation of chemicals.

Suppliers and distributors are monitored for compliance with the Code; those who do not comply are not to be used in future by member companies of the programme. Similarly, the Code stipulates that if particular customers are not prepared to comply with those aspects of the Code that are related to dealings with them, member companies will not be permitted to sell products to those customers.

Hazardous Waste Management

This Code covers all aspects of hazardous waste management including storage, transportation, treatment, disposal and destruction of chemicals as well as the care and closing down of hazardous waste sites. Member companies are encouraged to find ways to reduce, reuse, recycle or recover hazardous waste, all of which are seen as options preferred to disposal of waste.

A key component of Responsible Care is the "Community Right-to-Know Policy". Each member company is required to have an active community awareness programme to reach out to and respond to community concerns. In the early 1990s, the federal government gave notice of impending requirements to reduce toxic emissions. The Canadian Chemical Producers' Association devised guidelines two years in advance of likely legislation being passed, including standards more stringent than those forecast for the legislation. The CPC regards the data collection and reporting aspects of these guidelines as flowing from the "Community Right-To-Know Policy". The National Pollutants Release Inventory Regulation, passed in 1993, sets out a process for data collection and reporting that is patterned partly on the earlier CPC initiative.

Implementation and improvement of the Responsible Care initiative is supervised through six regional leadership groups. Each of these is centred in a major chemical-producing part of Canada, for example, Calgary, Alberta, and Montreal, Québec. Four groups are in the industrial area of southern Ontario. These groups of chief executive officers of companies meet regularly to assess compliance with the Codes of Practice and to assist each other in making progress within their own companies.

III. ROLE OF GOVERNMENT IN IMPLEMENTING THE ALTERNATIVE

The Government has not had an active role in implementing the Responsible Care initiative, although the programme did evolve largely from early policy research done by a government department. This took place in the context of stakeholder consultation, and involved a framework for "life cycle management" of chemicals, devised by Environment Canada. The six Codes of Practice owe much to that early scenario, and certain aspects of the programme are still based on the original proposal, notably the structure of regular meetings of industry executive "leadership groups".

It can be surmised that continuing efforts at strengthening environmental legislation by both federal and provincial governments added impetus to efforts by industry to pre-empt the possibility of regulation through effective self-discipline.

Since the government has not been actively involved in implementation or supervision of the Responsible Care scheme, institutional changes were not needed to carry out this alternative to regulation.

In recent years, however, government representatives have played some part in stakeholder consultation groups related to each of the six Codes of Practice. There has also been considerable consultation between industry and counterparts in government on issues (e.g. transportation of toxic chemicals) in which there are mutual interests.

In some areas, governments have actually adopted the Responsible Care guidelines, rather than being the catalyst for creation of the guidelines. This is particularly true with respect to the procedures detailed in the Code of Practice dealing with emergency response. Although the guidelines deal with emergency response to chemical-based problems, the procedures have some applicability for responding to other types of community emergencies as well. Consequently, a number of provincial and municipal government agencies have adapted the Emergency Response Code of Practice for their own general use in planning general emergency response.

IV. EXPERIENCES AND ASSESSMENT

a) Effectiveness

In 1994, CPC issued reports indicating that since 1992 CPC member companies had reduced their total emissions of substances, 50 per cent. They projected a further reduction of 50 per cent in overall emissions by 1999. A steady decline in workplace accidents and transportation accidents was also noted.

In order to conform to the Codes of Practice, companies have had to carry out systematic assessments of their operations, and in doing so have discovered shortcomings in procedures that would not otherwise have been noticed. Consequently, some companies are operating more efficiently, and a few

have saved money as a result of conservation measures. These positive results are in addition to the benefits to employee health and safety, as well as the reduction in exposure to possible lawsuits or financial loss resulting from unknown or unforeseen environmental damage.

There have also been benefits to the public image of the chemical industry, as well as to the self-esteem of executive officers who have been involved in the programme. There have been clear benefits in the sense that implementation of the Responsible Care programme has been a useful management tool for assessing and improving many facets of company operations.

The success of the programme can be measured partly by the number of countries (more than 35) who have sought to follow the Canadian lead by instituting similar programmes. It can be observed that the international group that acts as a forum for such programmes was initially chaired by a Canadian official, one of the chief officers in charge of the programme with the Canadian Chemical Producers' Association.

An unexpected benefit of Responsible Care has recently come to light. One company reported to the CPC Board of Directors (which oversees Responsible Care) that a banking institution gave it reduced loan rates because it was participating in the Responsible Care scheme. Because of the procedures mandated by the plan, the bank felt that the company was more likely to be successful and less likely to become liable for damage caused to the environment. One can speculate that there may be benefits down the road in terms of insurance rates as well.

One achievement of the Responsible Care initiative has been the success of its organisers in persuading participating businesses to disclose information about company practices that might help competing firms to meet Responsible Care objectives. It appears that when the Responsible Care plan was in its formative stages, some companies were concerned about sharing information on individual corporate practices, fearing they might reveal business secrets to competitors.

b) Costs and difficulties

It is not possible to know how much traditional regulatory approaches might have cost government or the private sector if the Responsible Care programme had not been instituted. Certainly, full enforcement of environmental protection laws would be very costly.

The private costs of the programme include the time of officials in each member company to take responsibility for the six areas covered by the Codes of Practice. This is in addition to the time taken by chief executive officers who participate in the regional leadership groups. But, as noted, there are sometimes net economic gains for companies because of the usefulness of the programme as a management tool.

One of the major problems with inaugurating and carrying out this programme was that some companies thought it was going to cost too much or be too difficult to implement. This problem was partly mitigated by the willingness shown by larger or more advanced companies to offer assistance to those who struggled with attaining the standards required by the Codes of Practice. One of the problems, particularly in the early days, was the public perception that the chemical industry was presenting a "green smoke screen" to avoid regulation, and that it could not be trusted to take the public interest adequately into account. The success of the programme, including the endorsement it has received from government officials responsible for environmental matters, has been ameliorative in this regard. However, a number of companies have left CPC at various times since the inception of Responsible Care. It is unclear whether the costs of implementation of the Codes were a factor in their decision to leave CPC, although the companies have never given this reason for leaving.

A compliance verification process was introduced in 1993. Verification inspections are observed by members of the National Advisory Board. A team of four persons independent from the company carries out the inspection. The inspection team reviews the management systems in place, partly based on interviews with company officials, suppliers, customers and people from the local community where the company (usually a manufacturing plant) is situated. One member of the inspection team must be someone who has the confidence of the local community, and who is obligated to report the team's

findings to that community. The inspected company is also obliged to describe the results of this verification process in a report to the CPC.

The inspected company pays the cost of the visit, which is about C\$ 10 000 to C\$ 14 000. By early 1996, 27 members had passed the review and another 25 were scheduled to be reviewed in 1996. The remaining (mostly new) 15 members are still implementing the codes.

c) Legitimacy

As was noted earlier, initial scepticism by regulated entities, the wider public, government administrators and political officials has largely been overcome. From the public perspective, there could be concerns with respect to accountability and transparency. There is, however, a National Advisory Panel, consisting of 12-16 individuals from across the country with interests in transportation, health and environmental issues. This group helped to draw up the protocols, and has met about four or five times a year since 1986 to review developments in Responsible Care and to critique performance.

Participating companies are also accountable to their peers. No one wants a tragic incident to tarnish the reputation of the membership or of the industry. Within the CPC, accountability is structured through regular reporting to the Board of Directors by the chairs of each leadership group.

The issue of transparency surfaces with respect to the identity of businesses who do not adhere to the guidelines. The name of the non-complying company who was eased out of the CPC has never been made public. It is the policy of the CPC to protect the confidentiality of its membership. That policy encourages participation, and facilitates disclosure of corporate practices to peers. Outside observers might prefer that companies refusing to comply with the higher standards should be exposed to public scrutiny.

It should be reiterated that the CPC involves companies who essentially supply other companies, rather than deal directly with consumers. Nevertheless, the general public is not able to learn whether the practices of a company that is no longer a member might endanger the health or safety of workers or of the general population, or might do damage to the environment. A general inquiry from a member of the public as to whether a company meets Responsible Care is of course possible in the same way one might ask a company whether it meets ISO 14000.

V. LESSONS LEARNED

Business and government agree that this voluntary approach has been well designed and has been implemented gradually but successfully. Moreover, during the latter part of 1993 and early 1994, verification protocols were installed to enable systematic reviews of compliance to be undertaken. Given that the Responsible Care guidelines were completed in 1989, and acknowledging that some companies had a more difficult time upgrading than others, particularly in a recession, one can still ask why assessment and verification procedures were being put into place only in 1993.

From the perspective of regulating the industry in the public interest, it seems likely that the degree of improvement in environmental sensitivity obtained through Codes of Practice would not have been achieved through command-and-control regulation. Moreover, the cost of enforcing regulations that would touch as many areas as the Codes of Practice would probably be beyond current levels of resources available to the public sector.

The threat of intervention by the government with command-and-control regulation has been an important incentive for the development of Responsible Care. However with the Programme in place for a substantial number of years the question now is whether this threat is still credible and remains an incentive to improve the Programme.

Although the Responsible Care initiative is innovative, it may not be easy to duplicate its success in other industries. In this case there was a deep concern among senior executives of chemical

companies that they might even lose their ability to continue making chemicals, for the reasons mentioned in the introduction. They basically had three options in order to respond:

- they could try to contain each regulatory initiative as it came up from governments;
- they could try to identify each individual concern of the public and then attempt to deal with these on a case-by-case basis; or
- they could fundamentally review all their operations and the life cycle of their products, and commit themselves to “doing the right thing”.

The first two options left the industry at the mercy of external forces and could result in a highly disjointed approach to competitive operations. Responsible Care is an attempt to seize at least partial control of the agenda and to demonstrate that chemicals and chemical operations are being dealt with safely and responsibly.

The concept of “doing the right thing” has a number of essential touchstones in this case: peers in other companies, the public – particularly in plant communities and governments. Because of this concept underlying Responsible Care and personal commitment to it by senior executives, executives and their employees focus on identifying the right thing to do in various situations arising in individual companies that are not always covered by legal requirements. There are some general lessons that can be derived from the Responsible Care experience.

a) Involving stakeholders effectively

All relevant players in the chemical industry had the opportunity to be involved in the design and implementation of the Responsible Care initiative. Government regulators first suggested the concepts that form the core of Responsible Care, and have been involved in consultations concerning the development and implementation of standards. Developing voluntary standards jointly by those in position to be aware of industry problems, public perceptions, technological advances and changes in administrative procedures allows for more practical and accepted standard-setting.

b) Public and industry education

Since one of the reasons for developing Responsible Care was the lack of a supportive public relations climate for the industry, it was important to adopt the public’s “right to know” as a governing principle. This involves both informing the public about risks and getting the word out concerning efforts the industry is making, through Responsible Care, to ensure that health and safety issues are dealt with in an effective and timely manner. Printed materials on the Codes of Practice are readily available and in language that is understandable to consumers and to staff in the regulated industry. An important component of success is staff training and procedures to verify compliance with internal control procedures within plants and companies.

c) Achieving wide industry participation

A measure of success of Responsible Care has been the degree to which industry members have signed on. One impetus has been the decision to make participation a mandatory condition for membership in the Canadian Chemical Producers’ Association. Still, it is problematic that some small manufacturers are not members of the CPC, and also that upstream suppliers and downstream users are not included in the Programme.

d) Monitoring of compliance and of programme performance

The Codes of Practice and operating Guidelines offer standards of assessment known in advance, which is desirable in monitoring. The various kinds of regular peer assessment, together with the new verification procedures, ensure that continuing watch is kept over individual companies as well as on the overall scheme.

Monitoring, apart from its role in creating public confidence, also has two internal functions. Firstly, it can assist the management of a company in assessing whether they need to dwell further on what is the right thing to do. Secondly, it can provide a greater degree of confidence in (the executives of) other companies that the initiative is being taken equally seriously by all companies and that they will not be jeopardised by others' behaviour.

There is no direct "complaints" procedure for non-compliance, except by industry members themselves operating in their own peer structures. Nonetheless, there are a number of outside incentives to motivate the industry and individual companies to adhere to the Responsible Care standards, such as the potential for stricter regulation, adverse media attention, and costly lawsuits if these standards are not in place and complied with.

There has been controlled introduction of the Responsible Care plan in practice. Before more formal inspection and assessment procedures were begun, executives involved in leadership groups and committees endeavoured to ensure that all participants first achieved a good measure of compliance, and volunteered advice, when needed, to help companies achieve objectives.

Developing a strong mutual aid network amongst companies and developing well-attended senior executive forums where both peer information and peer pressure may be nurtured are very important underpinnings for an initiative such as Responsible Care. A strong mutual aid and trust network needed to be developed before introducing more or less formal compliance monitoring with emphasis on sanctions such as expulsion from an association. Rejection of a company, whether by expulsion or other means, may have to be resorted to in certain instances, but could be considered as a sign of failure of the system.

THE ADVERTISING STANDARDS AUTHORITY AND THE SYSTEM OF SELF-REGULATION IN THE UNITED KINGDOM

by

Caroline Crawford*

I. PROBLEM TO BE SOLVED

Ultimately, advertising is designed to sell and, in order to achieve this purpose, it has to enjoy the confidence and trust of its audience. When, in 1955, independent television began broadcasting commercials, they were required to conform to a single statutory code controlling their content. Whilst there had been a variety of voluntary codes for non-broadcast advertising before then, no attempt had been made by the advertising industry to bring these rules together as a coherent whole. Strong pressure from consumer movements and the existence of the code of practice for television commercials were convincing arguments for a similarly unified system of control for non-broadcast advertising. The essential ingredient, though would prove to be the recognition across the advertising industry that the absence of such controls could be fatally damaging to the one thing it needs in order to be an effective medium – its credibility.

This enlightened self-interest on the part of advertisers, their agencies and publishers meant that a self-regulatory system for advertising control was achievable.

II. DESCRIPTION OF THE ALTERNATIVE

The Committee of Advertising Practice (1961)

The Advertising Association, the industry's trade association, initiated the task of drawing up a unified code of practice and establishing a system to enforce it. Discussions with other advertising trade associations identified a shared interest in ensuring that advertisements were trusted. As a result, representatives from all sectors of the industry came together to form the Committee of Advertising Practice (CAP) in 1961. It produced the first edition of the British Code of Advertising Practice the same year, which was based on the International Chamber of Commerce's International Code of Advertising Practice, first published in 1937.

The Advertising Standards Authority (1962)

Originally, no provision was made for any independent supervision of the industry's self-regulatory arrangements. However, within a year of the establishment of CAP and the publication of the Code, it became clear that the system would not gain public confidence and might be perceived as a biased cartel unless it was seen to be subject to regular independent scrutiny.

The need for external and credible scrutiny of the industry's system of self-regulation led to the establishment of the Advertising Standards Authority in 1962. Its chief tasks are still to promote and

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enforce high standards in advertisements, to investigate complaints, to identify and resolve problems through its own research, to ensure that the system operates in the public interest and to act as a channel for communications with those in the UK and internationally who have an interest in advertising standards.

The ASA is a limited company, and is independent of both the government and the advertising business.

ASBOF (1974)

The Advertising Standards Board of Finance was set up by the advertising industry in 1974 to provide a proper funding system for the work of ASA and CAP. The workings of ASBOF are explained more fully under section IVb.

The ASA Council

The Chair and at least half of the twelve-member Council appointed by the Chair to govern the ASA are unconnected with the advertising business. Council members sit as individuals and are selected, as far as possible, to reflect a diversity of background and experience. Members serve for a period of three years which can be renewed for a further three-year term. In 1995, for the first time, the ASA Chairman placed advertisements in the national press to invite new applicants to be interviewed as Council members. This provided a broad spectrum of applicants from which two new Council members were selected. Applicants were invited to demonstrate their ability to make sound and considered judgements.

The ASA Chairman is appointed by the Chairman of ASBOF to serve a renewable four-year term of office. He or she must be independent of the advertising business and of sufficient public standing to command the authority and respect needed to ensure the confidence of consumers, government and industry alike.

The ASA investigates complaints from any source against advertisements and promotions in non-broadcast media. Companies are told the outcome of the ASA Council's rulings and, where appropriate, are asked to withdraw or amend their advertisements or promotions. The adjudications reached by the Council at its monthly meetings, as well as editorial guidance on current topics, are published in the ASA's monthly report. This is distributed free of charge to European companies and institutions, the media, libraries, government departments, politicians, businesses, consumer bodies and the public.

Equal emphasis is given to conducting a substantial research and monitoring programme by reviewing issues, advertisements and promotions that fall within the scope of the Codes. Particular media and product categories are also selected for scrutiny. In this way the ASA can identify trends and prevent future problems.

Publicising the ASA's policies and actions is essential to sustaining wide acceptance of the system's integrity. A comprehensive programme of seminars and speeches, advertising, leaflets, briefing notes on a wide range of topics, a video targeted at consumers and educational establishments and articles written for professional journals, newspapers and magazines all augment the ASA's extensive media coverage.

The ASA is recognised by the government and has been examined by the judiciary: it provides an effective complement to UK and EC law.

The Authority operates in the public interest and in co-operation with the whole of the advertising industry by ensuring that everyone who commissions, prepares, places and publishes non-broadcast advertising observes the requirements of the Codes.

The Committee of Advertising Practice (CAP)

The Codes, which are written and enforced by the Committee of Advertising Practice (CAP), contain the rules governing the content of all non-broadcast media in the UK. CAP comprises 21 advertising

industry trade and professional bodies representing advertisers, promoters, their agencies and the media. CAP also administers the mandatory pre-clearance of cigarette advertising, provides free and confidential pre-publication advice to advertisers and promoters, their agencies, the media and others and co-ordinates the sanctions operated by its members to achieve the highest degree of compliance with the Codes.

CAP and ASA share a joint secretariat of 62 staff.

The Chair of CAP is elected by its members and normally holds office for two years. The Chair is succeeded by the Vice Chair, who is elected in the same way; both usually come from businesses with advertising interests. CAP meets six times a year and reviews recommendations made from its members to amend the Codes. When the Codes are subject to major review, CAP actively invites a broad round of consultation amongst interested non-industry parties, such as NGOs, government departments and interested MPs.

The Codes are contained in a ring-binder format so that if any clarification or additions are required they can be updated easily. In practice, since the Codes are framed around basic principles and can be interpreted in the spirit as well as to the letter, such changes are normally matters of interpretation of existing requirements. New points of interpretation can be communicated to the advertising industry through the ASA's monthly report, Ad Alerts to the industry, and seminars.

Much of the detailed work of CAP is carried out by its two standing Review Panels which meet regularly, or by one of its *ad hoc* Working Groups. The General Media Review Panel concentrates on all advertising, media and issues other than those relating to sales promotions, direct marketing and mail order, while the Sales Promotion and Direct Response Review Panel, as its name suggests, is responsible for these sectors. Each Review Panel is composed of industry experts together with one ASA Council member.

The Panels guide the industry and the secretariat by interpreting the Codes both in individual cases and on broad issues. They also provide a forum to guide pre-publication advice.

The Codes establish a standard against which advertisements can be assessed. They contain general and specific rules which are built on the following basic principles that all advertisements and sales promotions should be:

- legal, decent, honest and truthful;
- prepared with a sense of responsibility to consumers and society;
- in line with the principles of fair competition generally accepted in business.

The Codes are applied in the spirit as well as in the letter. Before submitting an advertisement for publication, advertisers must hold documentary evidence to prove all claims, whether direct or implied, that are capable of objective substantiation: the burden of proof therefore rests with the advertiser.

Sanctions

If an advertisement breaks the Codes, advertisers are expected to amend or withdraw it immediately. On the rare occasions when an advertiser chooses not to comply, a number of effective sanctions are available:

Adverse publicity. The ASA's monthly reports contain details of complaint adjudications, including the names of the advertisers, agencies and the media involved. The reports are circulated to the media, government agencies, the advertising industry, consumer bodies and the public. Published cases receive extensive press coverage.

Withdrawal of advertising space. Publishers and poster contractors can refuse further space to the advertiser. This sanction is often part of their standard contract for the acceptance of advertisements. In case the advertiser refuses to withdraw the misleading advertisement, the ASA will inform all publishers and poster contractors to ensure that the misleading advertisement will not be printed elsewhere. The vast majority of the media covered by the Codes adhere to this.

Removal of trade incentives. Both advertisers and their agencies may jeopardise their membership in trade or professional organisations. This can result in the loss of financial and other trading benefits.

Legal proceedings. Ultimately, the ASA can refer a misleading advertisement to a government department, the Office of Fair Trading. The Director General of Fair Trading can obtain an injunction in court to prevent an advertiser using the same or similar claims in future advertisements (ASA, 1988). In addition, injunctions may also cover the advertiser's agency and the media in which the advertisement appeared and can relate to a company, group or named individual. A breach of a High Court injunction is a contempt of court and can be subject to fines or imprisonment.

III. ROLE OF GOVERNMENT IN IMPLEMENTING THE ALTERNATIVE

Prior to the establishment of the ASA in 1961, the government kept a watch on the system of advertising control through the Board of Trade (now known as the Department of Trade and Industry). The then President of the Board of Trade appointed the Molony Committee on Consumer Protection in 1959 and the Advertising Association kept the Committee informed on its progress in establishing the self-regulatory system. The final report of the Molony Committee in 1962 concluded "that the new arrangements proposed by the Advertising Association hold sufficient promise to deserve a fair trial as the means of disciplining such advertising as is not restrained by duly-amended Merchandise Marks law and other existing legal measures". It added that "we do not think it necessary to propose a further statutory control, whether as an alternative or as a supplement to the voluntary system ... we are satisfied that the wider problems of advertising ought to be, and can be, tackled by effectively applied voluntary controls". The Committee, however, added that their conclusion depended on the satisfactory working of the system and in particular the independence of the ASA from the advertising industry.

In 1974 under a Labour government, the then Secretary of State for Consumer Affairs, Mrs. Shirley Williams and the Director General of Fair Trading, John Methven, threatened to impose legal controls on advertising unless the self-regulatory system was made tougher and more effective. The industry responded quickly by introducing a tougher Code and a more elaborate mechanism to administer and finance it. The Advertising Standards Board of Finance (ASBOF) was set up to raise more funds for the self-regulatory system to finance an extension of the activities undertaken by the ASA and CAP. This included an annual advertising campaign to promote awareness of the ASA inviting consumers to address their complaints to the Authority. The Code was revised and expanded and a second code for sales promotions drawn up (1975). Selective monitoring of advertisements was introduced to provide a measure of protection for the public without the need for a complaint and monthly reports of the ASA Council's rulings were published.

Since then the self-regulatory system has been the subject of scrutiny by government on two further occasions: by the Office of Fair Trading (1978) and by a Department of Trade working party (1980).

The DTI working party concluded that "Codes of practice provide a positive approach to advertising control. They can reflect the spirit rather than the letter and can be readily reviewed to take account of changing social conditions and attitudes. They command a high degree of commitment from the business community and encourage high standards of advertising to the benefit of consumer and advertiser" (Department of Trade, 1980).

The investigations by both bodies concluded that in general the system worked well. However, both also suggested legislation to provide self-regulation with a more satisfactory framework to operate within.

This framework was introduced following the introduction of the European Community's Misleading Advertising Directive in 1984. Enacted in the UK through the Control of Misleading Advertisements Regulations 1988, the legislation recognised the ASA as the "established means" to deal with the content of advertising. Although the ASA's existing sanctions are normally sufficient to secure the withdrawal of a misleading advertisement, the Regulations provide a long-stop measure for persistent or deliberate offenders through the regulations enforced by the Office of Fair Trading.

IV. EXPERIENCES AND ASSESSMENT

a) Effectiveness

The strength of the UK's system of self-regulation depends on the long-term commitment of all those involved in commercial communications. Practitioners in every sphere share an interest in seeing that advertisements and promotions are welcomed and trusted by their audience; unless they are found to be acceptable and believable, advertisements cannot be effective. If they are offensive or misleading they discredit everyone associated with them and the industry as a whole.

It is estimated that over 25 million advertisements appear in print each year in the UK, some 100 000 posters and 2.8 billion items of direct mail. Recent research conducted by the ASA reveals industry compliance rates of 85 per cent for direct mail, 96 per cent for press and 98 per cent for poster advertising, demonstrating a very high level of commitment with the Codes.

There are a number of important benefits that are apparent with the self-regulatory system supervised by the ASA:

Cost effectiveness. Costs are borne by the industry who have agreed to support the system through a voluntary levy. This means that costs are not imposed on the government or the consumer: the only cost involved in making a complaint, since the ASA asks of controls provides the maximum level of consumer protection and choice. The Codes are easily adapted to the development of new products or media, such as the Internet, and new advertising issues. They are kept under regular review and can be updated quickly in response to industry and consumer needs. The self-regulatory Codes can deal effectively with areas that are difficult to control by legal methods such as subjective matters like taste and decency.

b) Costs and difficulties

Initially the industry body, the Advertising Association, agreed to finance the ASA for at least three years. However, a more comprehensive funding system was established in 1974 when a tougher Code and a more comprehensive system for enforcing it were introduced.

The new funding arrangements were organised through the Advertising Standards Board of Finance (ASBOF). ASBOF collects a levy of 0.1 per cent of display advertising expenditure which equates to £1 in every £1 000 spent on advertising space. An additional surcharge of 0.2 per cent was levied on the direct marketing industry in 1992 when the Codes' remit was extended to cover the use of mailing lists for direct marketing. The levy is voluntary but provides sufficient funding to ensure the effective operation of the self-regulatory system. The ASA's operating costs for 1995 were just under £3 million. There are no costs to the government and the only cost for consumers is the price of a postage stamp in sending complaints to the ASA.

ASBOF also acts as a buffer between the Authority and the industry it regulates so that the independent judgement of those who administer the system is not compromised by any influence from those who pay for it.

c) Legitimacy

Official recognition of the ASA has gone hand in hand with increasing public awareness and recognition. Independent research conducted in 1996 reveals that the ASA is well known and well respected by the general public. Most consumers consider the ASA to be an effective regulator (78 per cent) and believe that it represents the most sensible way for advertising complaints to be dealt with (76 per cent). Notably, 64 per cent of respondents considered the existing controls exercised by the ASA to be effective, while three-fifths of the sample (61 per cent) chose to stay with the current system in preference to regulation by a government body.

The ASA also sustains a high level of transparency in its decision-making processes so that it is seen to be fair and publicly accountable by publishing its decisions and its appeal mechanism.

Decisions can be reconsidered if new evidence emerges after the ASA has made its decision or if a substantial flaw can be shown in the quality of the decision made.

By being autonomous from both the government and the industry it regulates, the Authority can maintain its independence and its neutrality, avoiding accusations of bias.

The ASA, as one of the founder members of the European Advertising Standards Alliance, has been closely involved with the development of new self-regulatory bodies in the Czech Republic, Slovenia and the Slovak Republic. The UK self-regulatory system has become a model for new and emerging systems of advertising control internationally and receives regular visits from government and regulatory officials from around the world who wish to draw on the ASA's experiences and expertise in advertising control.

Through its membership of the European Advertising Standards Alliance and its international links with regulators, the Authority is also able to share and compare information with other countries.

V. LESSONS LEARNED

Characteristics of the sector

The advertising sector depends highly on the trustworthiness of their product. The trust of consumers that the advertisements are legal, decent, honest and truthful is vital. Therefore it was very much in the interest of the sector to establish the codes and to create a credible oversight body.

Code development

This was initially done only by the sector, but a mechanism for consultation with non-industry interested parties and the public has been established which allows for continuous improvement of the codes.

Independent oversight

An oversight mechanism has been set up through both active monitoring of the sector by the oversight body and an individual complaints mechanism. Independence has been made credible through a special system of voluntary levies and a special board (ASBOF) administering the funding. ASBOF acts as a buffer between the industry and the CAP/ASA.

Communication of the Codes

In a system that relies partly on public awareness of the Codes' existence and partial oversight by the public through an individual complaints mechanism, it is important to have an active policy on keeping the public informed. CAP/ASA have a well-developed communication strategy.

The role of government

The government has played an important role by its initial endorsement of the system of self-regulation and later government reviews which led to a better Code and system to administer it. Also a legislative framework was created in which this system of self-regulation is recognised and that provides it with a long-stop measure to complete the range of sanctions to ensure compliance with the system.

How could self-regulation be designed to achieve better results?

The ASA has been examined in detail by two government departments (1978 and 1980) as well as by an Advertising Association Committee of Inquiry in 1987. These reviews looked into ways that the self-regulatory system could be improved and, as outlined earlier in this report, a number of developments have taken place since the establishment of the system in 1961 to take account of proposals to enhance the system. Following the Report of the 1987 Inquiry, the Advertising Association concluded

that they were "re-assured, though not lulled, by their judgement that in spite of recent proliferation both in media and in regulatory bodies, the systems in place are by and large working satisfactorily in the interests of both the business and the public" (Advertising Association, 1987).

There are those who think that the system would operate better if fines were introduced. However, the current armoury of sanctions already achieves a very high compliance rate and companies could write fines off against business expenses. The system works at its best when it prevents breaches rather than punishes offenders.

The balance of industry commitment combined with coercion for those who choose not to comply with the Codes achieves a high success rate. Rates of compliance with the Codes measured in the ASA's National Advertising Review in 1995 were 98 per cent for posters and 96 per cent for press.

Although the system is often referred to as "voluntary", this does not tell the whole story. The term "voluntary" normally applies in instances where individuals opt in or out of their own volition with impunity. Yet the system of advertising control is one from which it is practically impossible to opt out. Through the whole industry stating their commitment to upholding the standards laid down in the Codes, sanctions can be effectively and easily brought to bear on those who have stepped out of line. Industry commitment ensures a level playing field for the industry and thus achieves the purpose of retaining public confidence in advertising.

Future developments

The future of the media and communications industry looks set to be one of constant evolution and technological change. Keeping track of future technologies and new channels for advertising messages, such as the Internet, are at the forefront of the Authority's work.

The challenge for the ASA and the CAP in the future is how to adapt past experience and apply this knowledge to the future requirements of the industry and consumers.

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THE COVENANT AS AN INSTRUMENT OF ENVIRONMENTAL POLICY: A CASE STUDY FROM THE NETHERLANDS

by

Kees Bastmeijer*

INTRODUCTION

Although covenant-like agreements had been made earlier in the field of environmental policy, the environmental covenant as such did not appear in the Netherlands until the mid-1980s. Over 40 environmental covenants have been adopted since 1985. There are major differences among individual covenants, some due simply to differences in subject or objective, some due to the fact that the instrument is still under development. Policy on when a covenant is suitable, what should be included in it, and what procedure should be followed has evolved over the years.

Given the differences among environmental covenants, it is difficult to talk about "the" environmental covenant in the Netherlands. We could restrict ourselves to one particular kind of covenant. This would give the reader an understanding of the pros and cons of this instrument, the role of the government, experience to date and lessons to be learned. However, focusing on one type of covenant means that we would overlook general developments (experiences, debates, etc.) regarding the use of covenants as an environmental policy instrument, developments which have had a major impact on the type of covenants being concluded today. The report is therefore divided into two parts:

- i) General: The development of the covenant as an instrument of environmental policy in the Netherlands. This part defines the term "covenant" and various categories of covenant in environmental policy (section 1). In section 2 the increased use of the covenant is discussed. Policy on situations where covenants may be used has crystallised out of experience gained over the years and debates that have been conducted. This is discussed in section 3. We then discuss the status and substance of covenants and prescribed procedures (section 4). Finally, we look at the future of the covenant as an environmental policy instrument in the Netherlands (section 5).
- ii) Specific: A case study of covenants that have been concluded with industry target groups. This part looks at the problem and describes the system laid down in covenants, the role of government in the implementation of covenants, experience to date, and lessons for the future.

This report focuses on covenants in the field of environmental policy. The word "covenant" may therefore be interpreted as "environmental covenant". But covenants have been used in virtually all areas of government policy in recent years. An initial survey by the Netherlands Court of Audit produced a list of 150 covenants. Many points discussed in this report, such as different categories of covenant, reasons for the increasing use of covenants, etc., probably also apply to covenants in these other areas.

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PART I: THE DEVELOPMENT OF THE ENVIRONMENTAL COVENANT IN THE NETHERLANDS

1. CATEGORIES OF COVENANTS

In the Netherlands, a covenant is generally understood as “a set of (written) agreements between the government and another party that is designed to realise policy objectives”. In this report, policy objectives relate to the protection of the environment.

Covenants have many different titles. The parties will not always call the agreement a “covenant”, but might use a term such as protocol, environmental policy agreement, administrative agreement, code of conduct, declaration of intent, accord, etc. However, the differences go beyond nomenclature. To give an idea of the diversity of covenants that exist in environmental policy, one can divide them into different categories, depending on:

- the parties involved;
- the subject;
- whether or not the covenant is legally enforceable;
- the relationship of the covenant to regulations.

These categories are examined in greater detail below.

Parties

In terms of parties, the following categories of covenants can be distinguished:

- a) Covenants to which only government bodies are party. Such covenants are generally called “administrative agreements”. One example might be a covenant between the environment ministry and a municipality regarding the way in which the minister and/or the municipality will exercise their powers in future.
- b) Covenants between national government and umbrella organisations in industry. These include covenants between government and an association on the environmental targets to be met by the sector in question. Depending on the subject of the agreement, the associations of municipal and provincial authorities and/or water boards might also be party to such a covenant. Individual companies and individual authorities might also participate.
- c) Covenants containing agreements between the government (national, provincial or local) and an individual company. For instance, a covenant between a municipality and a particular company on joint research on environmental protection.
- d) Covenants between government (central, provincial or local) and one or more environmental groups. For instance, agreements on the involvement of environmental groups in certain policy processes, public information campaigns, etc.

Subject

Covenants concluded in the Netherlands in the field of environmental policy can also be categorised according to subject:

- a) Covenants on environmental aspects of products. For instance, covenants in which national government and manufacturers’ associations and/or individual manufacturers agree on the substances used in a product (e.g. batteries, spray cans). Another example might be agreements on the recovery and recycling of used products, information to be presented on the product, etc.
- b) Covenants on environmental pollution caused by companies (“establishments”). Such covenants can be concluded at different levels, e.g., with sector organisations or individual companies.

- c) Covenants containing agreements on how government bodies are to exercise certain powers in the future.

Many covenants will be mixtures, containing for example agreements both on products and the use of powers.

Legal status

Covenants have differing legal status:

- a) Non-legally enforceable covenants ("gentlemen's agreements" or "declarations of intent"). In such covenants, the parties agree to make certain efforts, which cannot be enforced in law, to achieve an agreed objective.
- b) Legally enforceable covenants. These are agreements under civil or administrative law which, under contract law, entail obligations for the parties that may be enforced by a court of law.

It is important to note that the name given to the covenant can be a source of confusion. In many cases, a covenant may be entitled "declaration of intent" or "code of conduct", suggesting that it is not legally enforceable, when in fact it is.

The function of the covenant in relation to law

Another characteristic used to categorise covenants is their function in relation to the law:

- a) covenants concluded as a stop-gap measure until legislation is in place (bridging function);
- b) covenants concluded in support of existing or future legislation (support function);
- c) covenants that replace legislation (independent function).

These distinctions are examined further in section 3.

It is clear that many different types of covenant exist, since a variety of combinations is possible. This report focuses on those in which the government reaches agreements with industrial associations, and other parties. Part I therefore examines:

- a) agreements with government;
- b) to achieve environmental objectives;
- c) on products, environmental pollution caused by companies and/or the way in which the government exercises its powers;
- d) which may or may not be enforceable in law; and
- e) which are intended as a stop-gap measure until legislation is in place, to support current or future legislation, or to replace current legislation.

2. THE RISE OF THE COVENANT

More than 40 environmental covenants have been signed since 1985. The popularity of the covenant over the last ten years has been partly due to the changing role of the government in environmental protection. There has been a growing realisation that unilateral imposition of regulations is not always the most effective approach.

The late 1980s saw the publication of the National Environmental Policy Plan (NEPP) containing a number of ambitious objectives. The Plan recognised that the co-operation of target groups (industry, agriculture, consumers, etc.) would be extremely important. Government and industry alike began to draw attention to the fact that industry bears responsibility for minimising the adverse effects of its activities. Talks between government and target groups on the most effective and efficient way to deal with environmental problems were the obvious next step. This "horizontalisation" of the relationship between government and industry had an impact on the government's use of policy instruments.

Legislation was not always an automatic course of action. It was recognised that new instruments could be used that were based on industry's new-found sense of responsibility – covenants, for instance.

Most of the covenants concluded in the 1980s covered environmental pollution caused by products (e.g. batteries, packaging, detergents). In general, little thought was given to enforceability. Most were gentlemen's agreements that were not legally enforceable.

As the number of covenants increased, so did criticism of the instrument. The main criticisms were:

- the "obligations" were too "soft": they were merely intentions to take measures, rather than obligations to achieve certain results;
- it was not clear whether obligations to take measures were legally enforceable; the status of the covenant was unclear;
- the covenant was gaining ground on legislation, which threatened to make parliament redundant;
- third parties had no role in the drawing up of the covenant; the process was not clear.

A former Environment Minister, Hans Alders, who took office in 1990, was initially sceptical about the use of covenants because of growing criticism. However, many covenants were concluded during his term of office (1990-1994). Actually, the Minister was critical of the situations in which covenants were used. On the basis of experience in the 1980s and growing criticism, a new policy – discussed in section 3 – was developed in the early 1990s. In addition, since 1992 a great deal of attention has been focused on the substance of covenants and procedures for drawing them up. These points are examined in section 4. The policy described in section 3 and the Dutch approach with regard to the substance and procedure of covenants, has not changed under the new Environment Minister.

3. POLICY ON COVENANTS

In recent years, the Ministry of Housing, Spatial Planning and Environment (VROM) has devoted a great deal of energy to developing a policy on using covenants, with particular focus on the extent to which covenants can be used as an alternative to substantive law. In short, the government prefers to use substantive law as a means of eliminating undesirable behaviour, but covenants may be appropriate:

- As a stop-gap measure until legislation is in place, for example in situations where there are too many uncertainties for legislation to be drafted (bridging function).
- To support existing or future legislation (support function). Examples include the covenants agreed with industry on the contribution particular sectors are to make towards achieving the objectives set out in the National Environmental Policy Plan (NEPP). These covenants are discussed in Part II.
- If they are likely to be more effective, perhaps because they save on implementation and enforcement costs, provided they are drawn up with due care (independent function). There are few examples of this in practice.

The above criteria apply particularly to the roles that covenants can play in achieving environmental policy objectives. Other aspects of using covenant are also important, such as the way in which a covenant is prepared and drawn up, its status, whether it is binding, and the elements that must be included in all covenants.

4. CONTENTS AND PROCEDURE

As more covenants were signed, it became more obvious that there were major differences in how this instrument was used. Some differences resulted from different objectives, parties, period of validity, etc. But other differences seemed to have no good reason. One covenant might contain regulations on evaluation, while others did not simply because the parties involved had not thought of it.

1992 CODE OF CONDUCT FOR ENVIRONMENTAL COVENANTS: A SUMMARY OF ELEMENTS

Contents

- a) Terms essential to the agreements in the covenant, and that might be open to different interpretations, must be defined.
- b) The subject of the covenant should be clearly explained.
- c) The parties to the covenant must be named, and it should be clear whether they are acting on behalf of others. If the authority to act on behalf of others has been granted, this authority should be appended to the covenant. If it is based on the articles of association of an organisation of companies, a copy of the articles should be appended.
- d) The covenant may contain an arrangement for the voluntary accession of natural or legal persons who are not original parties to it.
- e) The objective of the covenant must be described (and details of any phasing, etc., must be given).
- f) Obligations must be clear in the covenant. The following points should be specified:
 - what party is subject to what obligation;
 - the nature of the obligation (result or effort);
 - any deadline for fulfilment of the obligation;
 - whether the parties wish for the obligation in question to be enforced by some means other than the civil law for contracts.
- g) The period of validity must be stipulated in the covenant.
- h) The covenant should lay down arrangements for consultation, should this be regarded as necessary for its implementation. A steering group might be set up to discuss questions arising from the implementation of the covenant.
- i) The covenant should indicate how implementation is to be evaluated in light of the objectives. It should be clear who is responsible for evaluation and what reference points are to be used. Evaluation may be contracted out to an independent body if all parties agree.
- j) The covenant should indicate means of dealing with uncertainties that arise from altered circumstances, such as new policy insights, legislation, economic situations, environmental conditions, technological advances and international situations, that fundamentally affect implementation of the covenant.
- k) The parties should consider the question of how disputes are to be settled. The covenant may, for instance, stipulate that disputes regarding the interpretation and compliance should be brought before a steering group or arbitration committee.
- l) When including obligations in the covenant, the parties should consider the question of what measures can be taken in the event of non-compliance or inadequate compliance.
- m) The covenant may include arrangements concerning access to information provided by the parties.
- n) The covenant or explanatory notes appended to it should indicate whether, to what extent and at what point in the preparation of the covenant consultations were held with third parties.

(continued on next page)

(continued)

- o)* The covenant should avoid conflict with EC law.
- p)* Arrangements made in the covenant should not contravene legislation and regulations (including the licensing system). The relationship between the covenant and legislation and regulations should be explained in detail in the covenant or explanatory notes.

Procedures

- a)* If a minister intends to conclude a covenant, he must inform both Houses of the States General in good time. He may decide to submit the draft covenant to both Houses if there are grounds for doing so in view of its content.
- b)* Before a covenant is concluded, notice must be given of the draft covenant if this is required by EC law.
- c)* The final covenant must be published in the Government Gazette (*Staatscurant*). The minister concerned may decide to announce the draft of the covenant in the Government Gazette and invite comments.
- d)* The minister concerned must send a copy of the final covenant to both Houses of the States General. The parties will decide whether it should be sent to the EC Commission.

Since the early 1990s, more attention has been given to standardizing the content of environmental covenants. Industry, government ministries and associations of local authorities (provinces, municipalities and water boards) supported development of a code of conduct for agreeing on environmental covenants. This would be a kind of checklist of the elements that should be included in the covenant and the procedures that should be followed. The code of conduct was finalised in June 1992, with the approval of all major players. The main elements in the code of conduct regarding content and procedures are summarised in the box above.

The desire for more uniformity in content and procedure was not limited to environmental covenants. In early 1994, the Ministry of Justice began drawing up general instructions for covenants concluded with national government, based in large measure on this code of conduct. In January 1996, the general instructions were adopted by the Council of Ministers.

5. THE FUTURE

Debate on the role and status of covenants as an instrument of policy will continue for some years. The covenant is likely to continue to play an important role in environmental policy, but in its current form it will never be regarded as a full alternative to legislation. In the future, the covenant will be seen primarily as a management tool to support legislation, or as a temporary solution until legislation is in place.

New debates are also likely to arise. For instance, the idea of declaring covenants universally binding might be considered. This would mean that arrangements that had been accepted by the majority of a sector would be declared as binding on the small minority unwilling to accept them on a voluntary basis. However, the idea requires further investigation since it is not free of risk.

Finally, it is important that, once a covenant has been signed, the government does not simply sit back and do nothing. It is only after the signing that actual implementation begins. There must be

sufficient openness about the process of implementation (towards the authorities, industry, the public and environmental groups) to safeguard the legitimacy of the particular covenant, and the future of covenants in general. Problems in implementation might, of course, lead to changes in the way covenants are used in the future.

PART II CASE STUDY ON COVENANTS WITH INDUSTRY TARGET GROUPS

INTRODUCTION

The development of the environmental covenant was discussed in Part I. We now turn attention to a particular category of covenants to give a clearer idea of the pros and cons of this instrument, the role of the government in the process, and the covenant's relationship to other instruments, such as direct regulation (legislation and licensing).

As stated in Part I, there are many different types of covenants. We will focus here on environmental covenants concluded with industry target groups. Such covenants are interesting for two reasons. First, they are commonly used. Such covenants will be concluded with about 15 industrial sectors. Second, these covenants deal with issues that many other countries are likely to face, so experience may be easily transferred.

I. PROBLEM TO BE SOLVED

Environmental objectives are stated in national plans. In 1989, national targets were set for six environmental "themes", to be reached in 1994/1995, 2000 and 2010:

- climate change, including a reduction in carbon dioxide emissions;
- acidification, mainly reducing emissions of sulphur dioxide, nitrogen oxides, ammonia and volatile organic compounds;
- eutrophication, limiting phosphate and nitrate in water and soil to that converted by natural processes;
- toxic and hazardous pollutants, significant reducing emissions of "priority substances" (e.g. benzene, phenol and heavy metals) to air and water and accelerating clean-up of polluted land;
- waste disposal, preventing waste and focusing on recycling and other useful applications;
- preventing or minimising nuisance, odour, noise pollution and risks to public safety.

The targets were not translated in the plans into measures to be taken by various "target groups" (agriculture, construction industry, transport, energy sector, refineries, industry and consumers). However, the plans did emphasize that these groups bear a responsibility to the environment. The government did not believe that targets could be achieved by means of direct regulation or a licence system, but recognised that an active approach on the part of the target groups and good communication between them and the government would be necessary.

The problem was therefore how to translate the national objectives into measures to be taken at individual sources of pollution. To maximise the chances that the targets would be met, this would have to be done in such a way as to prompt the target groups into living up to their environmental responsibilities.

Below we set out how objectives are translated to the level of different industrial sectors and, ultimately, individual companies.

II. DESCRIPTION OF THE ALTERNATIVE

Declaration of intent

The covenant plays an important role as an instrument for implementing environmental policy. In the 15 selected sectors, which together account for 90 percent of environmental pollution caused by

industry, agreements are made between sectoral associations, central government and other authorities (provinces, municipalities and water boards) on how environmental policy is to be given substance over the next few years. These agreements are laid down in a "Declaration of Intent Regarding the Implementation of Environmental Policy". Despite the title, these agreements are in fact legally enforceable. They are not an alternative to direct regulation, but are designed to support the application of general regulations and the licensing system. This is clarified below.

Integrated Environmental Targets for individual sectors and translation to the level of individual companies

An important element of these covenants is the Integrated Environmental Target (known by the acronym IMT), which sets out objectives for the sector. The IMT will ultimately have to be achieved through the efforts of individual companies. In developing IMTs, industries are divided into homogeneous and heterogeneous sectors.

In homogeneous sectors, consisting of companies that are highly similar in the processes they use and associated environmental problems, a standard approach can be taken. A standard package of measures to be taken by each company (the "implementation plan") is developed on the basis of the IMT for the sector.

As stated, the agreements do not replace direct regulation (legislation and licensing). The measures to be taken by each company therefore ultimately have to be formalized, perhaps in the form of general rules providing exemption from a mandatory licence. If mandatory licensing is to be retained, the measures can be formalized through the licensing system itself (tightening up existing licences). It would also be possible to use the standard package of measures as the basis for granting licences, although it would have to be determined on a case-by-case basis if deviation from the standard package is necessary.

A covenant of this kind has been concluded with the printing industry.

In heterogeneous sectors, companies differ significantly in terms of size, processes, environmental pollution, etc., making it impossible to set a standard package of measures for the entire sector. Measures to achieve the IMT must therefore be determined for individual companies that will then be subject to licensing under the Environmental Protection Act, and perhaps other environmental legislation, such as the Pollution of Surface Waters Act.

The key to covenants with heterogeneous sectors is the agreement that each individual company will draw up a corporate environmental plan (BMP), in which it shows how it can best contribute to the objectives. The draft plan is submitted to the licensing authority for approval before finalisation. Once the final plan has been approved, it is used as the basis for issuing the licence. However, because of third-party consultation and appeal procedures, there is no guarantee that the licence will correspond exactly to the plan.

Since parts of the plan are formalized in the licence, enforceability is guaranteed. It is important that the corporate environmental plan be reviewed at least every four years. Since updated plans also have to be assessed and formalized by the competent authority, there is no danger that the licence will become obsolete. In this way, the authorities can meet their statutory duty to check regularly that the licence is still adequate in the light of new technological developments or changes in environmental quality.

Covenants of this kind have been concluded with the base metals industry (1992), the chemical industry (1993) and the dairy industry (1994).

A key idea is that both homogeneous and heterogeneous sectors should take an integrated approach to environmental problems. This is consistent with developments in environmental legislation. The Environmental Protection Act that came into force in March 1993 was an integrated piece of legislation, incorporating several old sectoral statutes. For instance, five important sectoral licensing systems (for noise and air pollution, nuisance, waste and chemical waste) were integrated into one licence. The covenant approach is fully consistent with this statutory regime. Companies in heterogene-

ous sectors develop their own views on short- and long-term integrated company environmental policy, and draw up plans on that basis. If the plan receives government approval, it is translated into licence conditions.

Parties

The actions to be taken are specified in the covenant and the parties signify their approval by signing it. The parties always include the sectoral association(s), central government and local authority associations. Depending on various factors, particularly the number of companies and the authorities concerned, individual companies and authorities might also sign the covenant. This happens as a rule in heterogeneous sectors.

Sectoral associations undertake various obligations for implementing the agreement, including motivating companies, providing support (e.g. in drawing up an environmental plan), negotiating with the government on any necessary amendments, conducting studies, etc. Individual companies that sign the covenant and that belong to a heterogeneous sector draw up a corporate environmental plan and review it at least every four years. They also report on the implementation of the plan. The role of the government in the implementation of these covenants is examined below.

III. ROLE OF GOVERNMENT IN IMPLEMENTING THE ALTERNATIVE

Information

Above all, it is the government's responsibility to provide information on the target group approach in general and the content of the covenants concluded in particular. Such information is primarily intended for the use of the relevant sectors, but provision of this information is important to ensure that the approach is accepted by the public and parliament.

Formalisation

In the case of heterogeneous sectors, the licensing authority will have to assess corporate environmental plans and ensure that they are formalized through the licensing system. In homogeneous sectors where mandatory licensing has been retained, the implementation plan will have to be formalized in a licence. If mandatory licensing has been abolished, it is the responsibility of central government to set general rules for the companies concerned.

Monitoring and enforcement

Besides formalizing elements of the corporate environmental plan or implementation plan, the government is naturally also responsible for monitoring and enforcing licence conditions and general regulations.

Other

There are a number of other specific government responsibilities connected with covenants. These include:

- supervising the implementation of covenants by consulting with the sectoral association;
- assisting with evaluation of covenants;
- promoting environmental policy at international levels to safeguard the competitiveness of Dutch companies;
- co-ordinating responses to corporate environmental plans with other government bodies, so that companies do not face contradictory opinions from different authorities (e.g. the province and the water board).

IV. EXPERIENCES AND ASSESSMENT

a) Effectiveness

The first covenant in the industrial series (with the base metals industry) was signed in March 1992. Three more followed in the printing, chemical, and dairy industries. Implementing these covenants requires setting in train processes that should have a long-term effect: the drawing up of corporate environmental plans, talks between government and the company, formalisation of the agreements in licences or general regulations.

It is still too early to draw hard and fast conclusions on the effectiveness of this covenant approach. However, early signs are positive. Companies are meeting their responsibilities and a process of consultation between government and industry is under way. To illustrate, the main conclusions of the first annual report (1993) on the implementation of the covenant with the base metal industry and the main conclusions of the first annual report (1995) of the chemical industry are summarised below.

- The process of drawing up and assessing corporate environmental plans is going well. In the chemical industry, three-quarters of companies had submitted definitive company environmental plans by the beginning of 1995. By May 1995, more than half of the plans had been evaluated by the competent authority (province or municipality). Most chemical companies needed the full 14 months to compile a plan. The companies for which municipalities are the competent authority had more difficulties than companies for which provinces are the competent authority. Only 3 of 126 companies have withdrawn from the agreement. For those companies, competent authorities have to take action.
- The added value from this new approach lies mainly in the fact that the process brings to light the integrated environmental problems of the companies, allowing environmental policymakers to learn lessons.
- By "adding together" the measures announced in corporate environmental plans, one can assess the extent to which the sector is likely to reach its targets. On the basis of the aggregated company environmental plans, the so-called "Consultative Group" of the covenant with the chemical industry expects the objectives for climate change, acidification, eutrophication and (waste) processing to be achieved. For dispersal, objectives will be achieved for two-thirds of the substances. Of course, this is a projection: the companies will need first to implement their environmental plans.
- The sector as a whole is accountable for the achievement in full of all the targets by the year 2000. The first step towards this will be a study, agreed on in the Declaration of Intent, on the achievement of the IMT. The second round of corporate environmental plans will show how the year 2000 targets are being met.
- Technical and procedural problems are also to be analysed.
- Considerable effort is put into implementation of the agreement, for example through brochures, seminars, etc.
- Special attention is given to the pursuit of international harmonization of the environmental policy. An international comparison of environmental policy for a number of relevant environmental themes was carried out in six EU member states.

b) Legitimacy

In the early 1990s, parliament in particular was interested in the use of covenants as an instrument of environmental policy. For several years, it has therefore been common for draft covenants to be submitted to parliament, with a view to possible talks with the minister. Parliament has not, incidentally, availed itself of this option very frequently in the case of recent covenants.

The first industry covenant, with the base metal industry, did spark off a great deal of debate, including in parliament. The debate centred particularly on the question of how the covenant stood in relation to the statutory system of environmental licensing. Before the covenant was signed it was sent

to parliament with an offer of talks if required. Parliament accepted the offer and before the covenant was finally signed, a debate took place between the minister and the Lower House. This focused particularly on the role of this covenant in environmental policy and its relationship to environmental legislation. Parliament was satisfied with the minister's explanation that covenants would not render the system of environmental legislation in general, and licensing in particular, obsolete.

In drawing up most covenants in the Netherlands, attempts are made to ensure the greatest possible degree of access to information. Most covenants state which documents are available to the public. This usually includes not only the covenant itself but also documents drawn up and exchanged by the parties during the negotiations. Any environmental group may, for instance, ask to see the covenant, corporate environmental plans and progress reports.

V. LESSONS LEARNED

As mentioned, implementation of these covenants has begun a long process. It is therefore too early to draw conclusions on the advantages and disadvantages of the approach. However, first impressions are that things are going well. A number of lessons can be drawn from our experience to date:

- The government and companies take different roles in this approach. Companies are expected to actively seek ways of integrating environmental policy into overall company policy, while the government plays a critical and assessing role. It is not simply a matter of discussions about particular installations (as was often the case in the past), but about short- and long-term integrated company environmental policy. In this regard, the corporate environmental plan is a strategy. The parties (government and companies) will have to grow into these roles, and initial experience shows that this cannot happen overnight.
- The companies for which municipalities are the competent authority seem to have more difficulties than companies for which provinces are the competent authority.
- Talks between the government and companies tend to focus more and more on the economic scope for environmental investment. Clear criteria must be formulated on this issue.
- It is assumed that companies will take an active approach and recognise that they bear a responsibility for reducing the burden on the environment. Tackling "free riders" who are unwilling to participate by tightening licences (i.e. those not preceded by a corporate environmental plan) involves substantial work for the government, but is an essential part of the approach.
- The integrated approach and the priorities associated with it are still in the early stages of development. The approach is still too much a sum of its sectoral parts.
- If the approach is to gain acceptance, it is important to emphasize that covenants do not obviate the need for legislation and licensing.

FLEXIBILITY THROUGH PUBLIC-PRIVATE PARTNERSHIPS: PREVENTION AND HARMONIZATION IN FDA'S SEAFOOD HACCP REGULATORY ALTERNATIVE

by
Daniel J. Chenok*

I. PROBLEM TO BE SOLVED

a) Underlying policy objective

The Food and Drug Administration (FDA), a component of the U.S. Department of Health and Human Services, oversees the safety of much of the U.S. food supply, including most seafood products. Under the Federal Food, Drug and Cosmetic Act (the Act), FDA is responsible for minimising the chance that consumers will purchase "adulterated" food. The Act defines adulteration as occurring if food "bears or contains any poisonous or deleterious substance that may render the food injurious to health", or "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health" [21 U.S.C. 342(a)(1), (a)(4)]. FDA seeks to control for food-related hazards that may lead to health problems, as well as those that do so.

FDA attempts to accomplish this mission through a variety of activities, mainly by setting and enforcing regulations and guidelines for entities that bring food to consumers (the agency also engages in education, research, and Federal-State co-operation on food safety). FDA directly regulates firms that process food, and FDA regulations have an indirect effect on entities that grow and harvest natural and artificial food products, transfer these products to processing firms, transport from processors to wholesale and retail operations, and sell to the consumer.

The seafood production network is complicated by the many different species of fish that, unlike other flesh food, are caught predominantly in the wild in international waters and transferred over long distances to processing operations. As a result, many additional sources of potential hazards that could cause adulteration are introduced. Yet FDA must ensure the safety of the nation's seafood supply based on the same standard that exists for other food with less complex production.

In addition, the U.S. seafood industry engages in significant levels of international trade. The United States is the world's second largest importer of seafood and over half of the seafood that Americans eat is imported. The U.S. is also the world's second largest exporter of fishery products and 30 per cent of U.S. fish products are exported. Thus FDA must achieve its central objective of maintaining seafood safety in a way that does not undermine the critical role played by trade.

Finally, all of FDA's regulatory activities must be consistent with Executive Order 12866, "Regulatory Planning and Review," in which President Clinton charges agencies with ensuring that where regulations are necessary, they are tailored to address problems; are based on a reasoned determina-

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tion of costs, benefits, and risks; are consistent with other relevant regulatory systems; and maximise flexibility for the regulated entity.

b) Problems with existing regulatory approaches

FDA has traditionally enforced seafood safety by targeting specific hazards that have been recognised as meriting a Federal response. A uniform national approach has then been adopted to address those problems, without regard to whether the problems exist consistently across firms. In a complex food production system such as seafood, where multiple risks exist in multiple settings, uniform approaches are likely to be too strict for some specific hazards while missing others entirely.

The U.S. seafood processing industry is comprised of approximately 4 800 firms. Small firms account for 75 per cent of this total, but for less than 10 per cent of seafood consumed in the U.S. To oversee this enterprise, FDA devotes some 400 inspectors (on a full-time equivalent [FTE] basis) for 3 000 of the firms, and relies largely on States to inspect the other 1 800 processors who work with shellfish. FDA can inspect 1 500 to 1 800 firms per year, meaning that high-risk processors may receive annual visits while companies shown to be safer may be inspected every two years.¹

FDA's traditional regulatory enforcement of the seafood industry has involved periodic, surprise, and required inspections of seafood processing operations and assessment of imports, including examination of sample food products. In addition, FDA assesses the extent to which seafood processors follow FDA rules for "current good manufacturing practices" (CGMPs), which contain general requirements for basic sanitation-oriented concerns but are by themselves not thought to provide adequate assurance of actual food safety. These traditional inspections lead FDA to draw conclusions about whether the regulated firm is operating safely. However, the burden of proof lies with FDA to identify and prove that safety hazards exist, and end-product testing of seafood for contamination is inherently difficult because the hazards are difficult to measure and the testing process itself can introduce potential adulteration; also, end-product testing can be expensive because the level of testing must be high to ensure that the result valid and not a chance occurrence. FDA complements this traditional enforcement with training and technical assistance, education, and research.

FDA's enforcement of the Food, Drug and Cosmetic Act is complemented by product liability law. U.S. consumers can and do bring suit against food processors, restaurants, and other entities in the food industry, based primarily on State laws and evolving case law at the Federal level. Most processors are aware of this liability risk and carry insurance to protect against it. Nonetheless, the threat of large court awards can add to their incentive to avoid the production and sale of hazardous products.

Over the past several decades, this existing approach has been complicated by a variety of factors that can increase opportunities for contamination, including: new technologies for food processing and packaging, increased contact with chemical products, and increasing imports. In addition, although FDA is not primarily concerned with the ability of U.S. firms to export food, it must work in concert with the regulations of other countries whose firms trade in seafood with the United States. All of this has led to several major problems under the existing framework for food safety regulation, which led FDA to pursue additional management tools for its mix of instruments used in seafood safety enforcement:

- FDA has seen increasing potential opportunities for food contamination, leading to health hazards that could ultimately result in a variety of food-related diseases. In addition to FDA's own observations, external studies drew this conclusion, including a study by the National Academy of Sciences (1991).
- The perception that FDA lacks a comprehensive programme to ensure food safety, coupled with widely reported anecdotes of health problems resulting from adulterated food, has led to diminished consumer confidence in seafood. Given the generally recognised health benefits of fish relative to other flesh food products such as meat and poultry, a decline in fish consumption could increase long-term health risks.
- The U.S. was not moving rapidly to match its regulations with a new system of regulatory enforcement introduced by many of our trading partners, especially Canada and the European

Union. U.S. firms faced threats that their fish exports would be banned unless this new system, known as Hazard Analysis Critical Control Points (HACCP) and described in more detail below, was adopted as a U.S. national standard approach.

- The rise in the number and cost of U.S. product liability lawsuits generally, largely due to increased attention to the courts as an avenue for consumer recourse, may be shifting primary incentives from providing safe food to establishing litigation protection.
- The existing system placed the burden on inspectors to find problems, rather than on the producer to demonstrate an understanding of hazards and design controls for those hazards. The existing system provided the inspector with a snapshot of the moment of inspection, rather than a comprehensive view of a processor's operations.
- The existing system relied on scarce Federal resources to control seafood safety through periodic inspections, rather than work with seafood producers to develop preventative measures that would minimise the risk of contamination before it ever occurred. In recent years, FDA has faced this increasing complexity with a relatively constant cadre of 400 FTE inspectors who must give greatest priority to the highest risks in the seafood supply and thus limit the number of traditional inspections. The existing system was not designed to address the potentially large number of firm-specific opportunities for food adulteration to occur, and to establish mechanisms to reduce the risk that they would occur in the first place.

II. DESCRIPTION OF THE ALTERNATIVE

a) Factors leading to the adoption of approach

In light of the problems identified above, FDA sought a new system for the enforcement of seafood safety that would leverage the actions of the thousands of seafood processors to build safety into their operations from the start. This system, known as "Hazard Analysis Critical Control Points", or HACCP (pronounced "Hassip"), was designed to: 1) strengthen the efficiency and effectiveness of current safety techniques by working with the private sector on prevention through a flexible management tool that had proven popular with some domestic firms; 2) increase consumer confidence in the nation's seafood supply; and 3) ensure continued access to imports and exports through greater international harmonization with an approach that had gained substantial international credibility.

HACCP is based on a system introduced in the 1960s by the U.S. firm Pillsbury, who sought to assure the safety of food consumed by astronauts in the U.S. space programme. Pillsbury discovered that the amount of end-product testing required to guarantee that no contaminants entered the astronauts' food supply caused a substantial decline in the amount of food available to eat. The company determined that a preventative system would place controls at critical points in the food production process where contamination risks were significant. U.S. and foreign firms increasingly adopted HACCP principles on a voluntary basis over the next three decades.

The Federal focus on adapting HACCP to seafood regulation was based on the complex and varied hazards that can jeopardise seafood safety in the U.S. Americans eat hundreds of species imported from well over 100 countries, most of this fish is caught in the open sea (as opposed to being farmed), fish is highly perishable, and is eaten raw more than any other flesh food. Federal involvement commenced in 1986 with the Model Seafood Surveillance Project (MSSP), in which Congress asked the U.S. Department of Commerce to design a seafood inspection system based on HACCP principles. This eventually led to a 1990 pilot project administered jointly by Commerce's National Marine Fisheries Service (NMFS) and FDA, which evolved into a voluntary NMFS fee-for-service HACCP assistance system for firms.

Foreign nations have been moving increasingly to HACCP approaches. Canada recently adopted a HACCP seafood inspection system, and much of Europe is introducing the initiative as well. A United Nations agency, the Codex Alimentarius Commission, recommended HACCP adoption for international use; many export agreements, memoranda of understanding, and mutual recognition treaties in the food trade area are expected to include HACCP or an equivalent system as a prerequisite. Indeed, both

the U.S. Congress and the domestic food processing industry have registered strong support for rapid adoption of an FDA final regulation that would lead to mandatory HACCP oversight for seafood,² in large part due to the need for harmonization with our trading partners. This is a major consideration behind making the alternative mandatory for seafood producers, rather than voluntary; although many firms could be expected to adopt HACCP voluntarily given firm-specific management of hazards in the production process, many others would not, which would be insufficient for international acceptance of U.S. seafood.

b) Design and operation of alternative

FDA introduced HACCP principles into seafood regulation in its 18 December 1995 regulation. Specifically, HACCP principles involve a programme of seven components that, if adopted by seafood processors, have been recognised internationally as minimising food adulteration risks before they occur. HACCP also establishes systematic mechanisms for improving operations when potential hazards are identified. HACCP places the responsibility to determine and control for problems with the individual firm, which allows for a varied and tailored approach to addressing risk rather than a one-size-fits-all regulatory strategy. Under HACCP, if one firm correctly determines that no hazard is reasonably likely to occur in a particular element of its production process, no HACCP controls are necessary, whereas a second firm processing a similar product may need to establish a control for the same production element due to a variety of exogenous factors.

FDA's final rule implements the seven HACCP components (FDA, 1994, pp. 7-11):

1. Hazard analysis: the identification of likely hazards that could occur in specific products as a result of specific processes, including microbiological substances, toxins, chemicals, drugs, and physical objects.
2. Critical control points (CCPs): the elements of the production process that are most important in terms of a failure to establish adequate preventative measures that could lead to potential health hazards.
3. Critical limits: the measured levels of performance of controls at CCPs (for example, a temperature range for refrigeration).
4. Monitoring: keeping watch of the CCPs to assess whether controls are within the critical limits.
5. Corrective action: the steps taken when monitoring indicates critical limits have been passed, including holding the product until safety has been evaluated.
6. Recordkeeping: recording and maintaining information about the results of monitoring, the taking of corrective actions, and verification.
7. Verification: reviewing all HACCP components periodically or when a production element changes.

These seven components are adapted to individual plants through the development of a firm-specific HACCP Plan. The Plan becomes a roadmap of how an individual establishment will manage its operations to ensure that safe practices embodied by HACCP are tailored appropriately to its own risks, some of which may be similar to those of competing firms and some of which may be unique. HACCP allows firms the flexibility to design their own production systems and manage their own processes, rather than following a more rigid requirement set by a central regulatory authority.

HACCP necessitates extensive knowledge of safe food procedures by at least one representative of the firm, since FDA relies on private sector self-implementation. Training of employees is important to the success of the HACCP alternative; FDA's rule has specific provisions about the knowledge necessary to ensure the introduction of a proper HACCP programme. FDA allows firms to meet these requirements through specific approved courses, videotaped information materials, or equivalent on-the-job training.

It is important to note that FDA's rule also contains specific requirements for sanitation, including monitoring and recordkeeping. While not explicitly part of the HACCP model, FDA – along with interna-

tional bodies, as evidenced by revisions to the Codex Alimentarius codes of practice for fishery products – finds that sanitation is an essential prerequisite if HACCP is to ensure food safety.³

Consistent with existing food safety law, FDA extends the reach of HACCP by placing responsibility for safety with the food processor, which includes the safety of the food the processor receives from domestic harvesters or foreign firms. The effect of the regulation reaches the point where food production begins, but not because the HACCP regulation directly affects all parts of that process. FDA essentially makes processors partners responsible for the safety of food that they receive.

At the same time, FDA has not mandated that food retailers and restaurants adopt HACCP principles. The agency is working with those industry sectors on voluntary implementation of HACCP; however, given the key role of the processor in food production, the need for international harmonization at that stage since foreign nations most often purchase from processors, and FDA's limited inspection resources, it was appropriate to place mandatory controls there.

III. ROLE OF GOVERNMENT IN IMPLEMENTING THE ALTERNATIVE

a) Implementation and monitoring

FDA initially sought comment on instituting seafood HACCP in a 28 January 1994 proposed regulation. This extensive rulemaking proposed mandatory adoption of HACCP for all domestic seafood processors. The 12 December 1995 final regulation responded to over 200 public comments, and made several revisions to the regulation to give greater flexibility and reduce private sector costs. Among the most important of these revisions was the extended effective date: rather than making HACCP mandatory after one year, firms would have two years to adjust. This allows for an extended period for a variety of activities that include training and technical assistance to firms (including small firms); reviews by FDA of early, voluntary HACCP plans to provide feedback on whether the plan would meet FDA's standards; the development of Federal-State partnerships between FDA and States with their own seafood oversight authority who wish to adjust to the new regulatory regime. In addition, the agency published a draft guide for comment on 7 April 1994, which provides examples of specific steps that FDA would likely view as acceptable ways to implement the seven components of HACCP described above; an interim first edition of this guide, published in July 1996, contains numerous revisions of the original draft based on public comment. FDA has also committed to significant consumer education and outreach as a supplement to HACCP.

While the processor plays the actual implementing role under HACCP, FDA retains a strong oversight presence through traditional inspections to the extent that the agency's resources permit. As FDA notes in the preamble to its final rule, "Industry ... must take primary responsibility for the production of safe food, while the regulator must be responsible for setting standards ... verifying that industry is doing its job, and taking remedial action when it is not" (FDA, 1995, Preamble Section I.B.4). But implementation of HACCP is expected to reduce the problems discovered in an inspection; if this does not turn out to be the case, the benefits of the rule would be called into question.

FDA will manage oversight through a new kind of tool, the HACCP-based inspection, after the rule becomes effective. This inspection is based on a review of the adequacy of the HACCP Plan, including a determination of the appropriateness of the critical control points, critical limits, and corrective actions as well as a review of monitoring and other records. The HACCP inspection adds to FDA's existing mix of enforcement activities by placing government in a different role than solely that of spot-check compliance auditor: since the firm becomes the primary implementer of a process to address its own hazards, FDA must adapt to the unique elements of each firm's production process. This is in many ways a more challenging exercise for the agency, but the HACCP approach ensures that government addresses specific and real risks.

Indeed, reliance on firms to adopt effective HACCP programmes places FDA in less direct control of reducing actual hazards than would be the case under existing regulatory enforcement. If firms do not implement HACCP responsibly, risks will presumably remain higher than necessary and consumer

confidence that seafood is safe may fall. As a result, every one of the nation's 4 800 seafood processors is likely to receive an inspection either before or immediately after the rule goes into effect.

FDA also plays a leadership role in educating foreign firms about the U.S. system, and in developing international agreements based on mutual recognition of HACCP principles. FDA currently is educating foreign nations and firms through briefing staffs of foreign embassies, attending international conferences and trade shows, helping to develop a "train the trainer" course in HACCP for individuals planning to conduct overseas training, communicating with U.S. importers (FDA, 1995, Preamble Section ILL.2.). In addition, drafting memoranda of understanding with seafood exporting countries can provide FDA with an avenue to ensure that foreign processors meet the same standards as domestic firms subject to FDA oversight. Conversely, the very fact that FDA published this rule prior to 1 January 1996 meant that the European Union did not have to decide whether to carry out its intention to boycott U.S. seafood on the grounds that without a HACCP system safety could not be guaranteed (FDA, 1995, Preamble).

In addition, FDA co-ordinates with other U.S. government entities on implementing HACCP. Its rule will likely eliminate the need for the separate Federal fee-for-service HACCP guidance programme run by the National Marine Fisheries Service; that agency has considered whether to privatise the programme (National Performance Review, 1996, p. 10). As stated, FDA also works with States who, in the U.S. Federal system, have separate oversight responsibilities, and the additional year before the rule becomes effective will allow further co-ordination of this kind. Perhaps most importantly, FDA co-ordinated the development of its regulation with that of the U.S. Department of Agriculture's Food Safety and Inspection Service, which is introducing a HACCP-based approach into the existing meat and poultry inspection system.

FDA is also responsible for ensuring that its regulation is based on a proper assessment of costs and benefits. In response to public comment, the agency made several key revisions and improvements to its assessment of the economic impacts of this rule. Still, many effects remain unquantified. The Department of Health and Human Services (HHS) has committed to a significant study of the effects of this rule following its promulgation, the results of which will be available in several years. Consistent with this activity, FDA is also working with the Centers for Disease Control, a sister agency within HHS, to improve seafood illness reporting systems.

b) Institutional changes

For HACCP to operate properly, FDA inspectors must be able to shift from a traditional regulatory inspection system based on general rules to one that relies on preventing problems before they occur through working with the private sector to understand and address firm-specific risks. The HACCP system requires FDA staff to become familiar with those procedural principles that are critical to ensuring safety. The agency indicates that it is conducting the proper training to ensure that its inspectors understand the need to be flexible in recognising that there can be more than one way to achieve seafood safety while applying their enforcement authority, but the outcome remains to be seen.

Taking preventive measures requires co-operation with industry if U.S. consumers are to continue enjoying the abundance of seafood to which they currently have access. If FDA were to take an adversarial approach to HACCP oversight, significant penalties and sanctions could cause firms to close rather than develop improved processes consistent with HACCP. The two-year period prior to the effective date, during which time FDA will work in partnership with seafood processors, should provide an appropriate transition period for the regulator and the regulated community to develop a new relationship under the HACCP-based enforcement system. Because the HACCP model originated in and is supported by the private sector, this transition should be relatively smooth.

Adoption of HACCP also signals the support of FDA and the Administration for harmonization with international standards. Rather than operate as if the domestic market exists in a vacuum, the agency has come to recognise that co-operation with trading partners is key to ensuring not only continued trade flows, but also the safety of food imports for U.S. consumption.

IV. EXPERIENCES AND ASSESSMENT

The following discussion of costs and benefits is drawn primarily from FDA's Economic Analysis of the final HACCP rule (FDA, 1995, Preamble Section IX).

a) Effectiveness

Systematic evaluation of the HACCP model's effectiveness has not yet been conducted. It is assumed that sound processes lead to safe food; this assumption seems valid, since establishing controls on production elements where risks are greatest should result in the minimisation of these risks before they result in actual hazards. But FDA's estimates of benefits from this regulation are based on a model that contains many assumptions about the rule's impact.

FDA's final economic analysis assumes that the rule will have total (net present value) benefits of anywhere between \$1 435 billion and \$2 561 billion. This figure is derived primarily from assumed decreases in illnesses as a result of HACCP implementation. FDA assumes that in the third year that the rule is in effect, when its impact should be fully realised, between 20 150 and 58 520 illnesses will be averted, with annual benefits ranging from \$45 to \$116 million. By comparison, FDA estimates 113 630 total seafood-borne illnesses.

Other benefits that FDA expects to result from this rule are largely unmeasured. They include improved nutrition if seafood consumption increases due to greater consumer confidence (although price increases due to HACCP-induced costs in the short run and the long-run limited seafood supply would to some extent offset such an increase), enhanced competition among seafood firms due to a uniform set of rules, increases in exports given harmonization with overseas HACCP rules, the introduction of cost-saving technologies in the long term as a result of the transition to HACCP techniques, and greater efficiencies in Federal enforcement on the assumption that HACCP will lead to less adulteration in the food supply. A seafood trade association commented on the last point, noting that HACCP allows for "more effective and efficient use of FDA resources, and less disruption of processing and importing for consumers" (FDA, 1995, Preamble Section II.B.1).

As will be detailed below, these empirical benefits estimates – which do not include the qualitative benefits – generally exceed the estimated costs of the rule, meaning that if the figures are accurate FDA has effectively followed Executive Order 12866; the agency argues that the HACCP alternative maximises net benefits. However, it should be noted that the lower bound of the benefits estimate, \$1 435 billion, is less than the upper bound of the cost estimate (\$1 482 billion). While the unmeasured benefits would be likely to tip the balance, which would be consistent with the Executive Order in that the rule's benefits would justify the costs, FDA cannot yet say with certainty that its benefits exceed the costs.

It should be noted that the lack of application of the rule to harvesters, and especially to harvesters of shellfish, means that a significant source of risk of contamination and thus adulteration – hazards in the ocean waters themselves – will not be addressed directly by this regulation. Although making food processors responsible for the safety of the food they acquire from harvesters will have some effect on those harvesters – processors of oysters, clams and mussels must specify in their HACCP plans that they will only accept shellfish harvested in approved waters – raw shellfish may still contain ocean-based hazards. The effectiveness of the rule is further limited by the fact that FDA did not include retail establishments. Although the agency is committed to an education campaign that will alert the industry and the public of seafood risks, at present seafood at the retail level remains unregulated in the HACCP framework and thus subject to the same safety risks that were identified for processors under the existing inspection system.

b) Costs and difficulties

FDA estimates the total costs imposed on the economy by additional measures taken to implement the HACCP rule at between \$677 million and \$1 482 billion. On an annual per-firm basis, the costs

range from \$4 800 to \$13 000 after the first year (first year costs range from \$6 400 to \$23 000 per firm, the result of initial expenditures to get HACCP up and running).

This wide range in cost estimates is explained by different assumptions used to measure costs. The lower bound is based on an FDA analysis of two hypothetical firms that adopt HACCP, and based on reported information from HACCP firms. FDA assumed 80 per cent compliance with existing rules for Current Good Manufacturing Practices (CGMPs); higher compliance presumably translates into a cleaner operation and lower costs in adjusting to HACCP. The upper bound is based on a National Marine and Fisheries Service study that assumed 20 per cent compliance with CGMPs, and was based on firm data but not from firms that had implemented HACCP. As with many estimates of this kind, the real costs likely lie somewhere between these figures. FDA's future study of the actual costs and benefits should help to clarify the cost effects.

The most visible difficulty in implementing the HACCP model has come from small firms, who find the procedural requirements of the rule difficult to comply with. Small firms have also requested a delayed effective date. FDA, however, believes that agency guidance includes a basic HACCP model that small firms could adopt, and that to grant exceptions would increase the risk of adulteration.

c) Legitimacy

The most significant measure of HACCP's impact is its support by both most of the seafood industry and among U.S. trading partners. A significant portion of comments on FDA's proposed regulation supported the rule as increasing consumer confidence in the seafood supply, improving the existing system based on CGMPs and end-product sampling, placing primary responsibility with industry to establish preventative measures for food safety, and levelling the competitive seafood market both in the United States and abroad. The president of a crab processing company that introduced HACCP voluntarily in 1993 commented on the positive effects that HACCP had on her firm: "We can say nothing but good things about HACCP ... We have fewer and fewer consumer complaints because our checks throughout the day enable us to catch things. Fewer complaints mean fewer refunds." (Barros, 1995)

A *Seattle Times* editorial paid similar tribute to HACCP:

Instead of imposing new rules from a distant bureaucracy, the Food and Drug Administration set up a process that included industry representatives. The result is a set of standards that seeks to avoid problems before they occur ... The result is a case study in common-sense regulation – rules that increase public safety without imposing counterproductive burdens on private industry.

(*The Seattle Times*, 18 December 1995)

The Administration demonstrated its confidence in the merits of HACCP by making it a key component in its effort to reinvent regulation of the U.S. food supply. Both FDA and USDA rules are featured in the President's "Reinventing Food Regulation" report. And as indicated earlier, Congress also expressed support for speedy issuance of the final FDA rule.

In addition, while praise for HACCP could be expected to lead to significant voluntary adoption by firms, many firms – and especially smaller firms – would not do so of their own accord given up-front costs involved in making the transition to the new system. Because FDA believes that HACCP will be more effective in maximising food safety, and because the international environment is moving toward requiring mandatory HACCP as a condition for accepting U.S. exports, the agency could not rely solely on positive legitimacy and gradual adoption through voluntary means. Moreover, FDA is reluctant to cede ultimate authority to firms given its statutory mission to maximise food safety; a regulation allows FDA to use its enforcement authority if necessary against recalcitrant actors. It remains to be seen whether continuing to employ this authority will be necessary if legitimacy of the HACCP model becomes recognised throughout the industry.

Finally, the Agriculture Department (USDA) regulation that will implement HACCP for meat and poultry inspection will have a real but indirect effect on the legitimacy of FDA's rule. If the implementation of Agriculture's rule receives the same support as the FDA rule by allowing firms the flexibility to

target hazards appropriately and prevent sources of adulteration from occurring, this will reinforce the support for the HACCP alternative. On the other hand, prescriptive USDA enforcement may undermine support for FDA's similar regulation.

V. LESSONS LEARNED

a) Comparison to traditional regulation

The alternative to traditional regulation embodied by FDA's HACCP regulation has several important advantages relative to a traditional inspection approach. First, HACCP leverages limited Federal resources; FDA manages seafood safety with an additional tool, placing responsibility for demonstrating an understanding of seafood safety, and for keeping appropriate records relating to seafood safety, with the seafood processing companies. This public-private partnership model creates an incentive for the company to ensure that its HACCP plan is operating at maximum effectiveness, which in addition to the presumed benefits of lower adulteration risk will result in favourable treatment from FDA should an inspection occur. In this way, FDA is giving firms ownership of the safety process. The HACCP alternative demonstrates how working with industry to place certain responsibilities with the firm can expand the agency's reach significantly and thus lead to the more effective and efficient achievement of national goals.

The HACCP model also appears preferable to traditional regulation in that it produces behaviour designed to prevent problems before they occur, rather than after food hazards have been discovered. Firms that use a HACCP plan to adapt the seven components of HACCP to their processes report – anecdotally at this point – a reduction in hazards. As importantly, the reduction is based on preventing hazards that may exist in the particular production lines of each firm. Rather than following one-size-fits-all edicts from FDA about problems that may or may not be present locally, the HACCP approach gives firms the flexibility to design their own operations and tailor their actions to conditions in their plants.

A final but critical advantage of HACCP as a U.S. regulatory alternative is its harmonization with the growing international movement to adopt HACCP. By increasing imports from countries that effectively implement HACCP models, FDA will reduce the need to recheck the quality of seafood so imported. The U.S. government can reap similar benefits by encouraging other trading partners to introduce HACCP into their own production systems. These benefits have corollary effects for the export of U.S. fishery products, since key trading partners including Canada and the European Union have moved toward mandatory HACCP. Development of international memoranda of understanding allow for improvements in trade based on principles agreed to in advance by the U.S. and other countries. Even if HACCP were found to have no measurable difference from traditional regulation in terms of actual improvement in seafood safety – an unlikely result but one still unrefuted by hard data – the trade benefits are likely to make HACCP an attractive alternative to traditional regulation.

b) How could the programme be improved?

To some extent, recommendations for improvement are premature since the FDA rule does not make HACCP mandatory until late 1997. However, based on the preceding discussion several measures may make the model more efficient, both in the U.S. and abroad. Additional improvements will become evident when FDA completes its future study of the actual costs and benefits of the rule, relative to the estimates provided in the regulatory analysis; this activity is critical if HACCP is to be placed into an accurate perspective. Additional independent study of the programme would help to identify other potentially attractive revisions.

Given FDA's limited resources for inspection, providing firms with greater incentives to implement effective HACCP programmes voluntarily – placing even greater reliance on public – private partnerships – will increase the likelihood of a successful transition to the new regime. FDA could target increased compliance assistance and relaxed enforcement, including penalty reductions if hazards are found, in firms that demonstrate good-faith commitment to HACCP. Although FDA considered and rejected the alternative of making the rule voluntary, if firms do more without pressure from their

regulatory agency then the agency is freed up to concentrate enforcement efforts more deeply on addressing serious food safety problems.

A second area for improvement could involve FDA devoting more attention to educating retailers and consumers at home and exporters abroad about the benefits of HACCP and safe seafood practices. Since FDA's HACCP rule does not reach either the harvester or the retail market directly, the agency must rely on other means to inform these sectors about the benefits of preventative approaches to safety. Although some would argue that the rule should be expanded to make HACCP mandatory for the entire seafood industry – seafood advocates believe that the FDA rule suffers from "a tremendous gap" in coverage (Burros, 1995), and FDA has requested comment on expanding coverage – FDA would be wise to retain the rule's present scope to determine its impact more precisely while expanding education and outreach efforts beyond seafood processors.

HACCP requirements could also be made more extensive for higher risk parts of the industry, and less extensive where risks are low. Two-thirds of the commenters who addressed this issue believed that FDA would improve the rule by adapting the requirements based on risks presented; for example, a producer with little history of adulteration could be required to implement only a portion of the seven HACCP components. FDA argues that it does not have the data to assign different regulatory provisions based on risk. Rather, FDA believes that HACCP by its very nature targets risks on a firm-specific basis. Still, further risk-based delineation of the rule's general requirements may be feasible as a result of the agency's forthcoming study of the rule's effects.

Because HACCP places significant responsibility with the private sector to ensure food safety, the industry has an incentive to ensure that unsafe food does not reach consumers, and the industry has broad support for this model and an interest in its success, third-party inspections and certification of HACCP adequacy may be appropriate. FDA's limited resources could be targeted at the most unsafe firms or sub-sectors, while the agency could recognise third-party organisations for the majority of inspections. Although FDA is generally reluctant to cede ultimate authority, given its belief that its statutory responsibility for food safety means FDA must be in the decision chain, the agency's existing partnerships with States for shellfish inspections demonstrate the feasibility of this approach. Third-party inspections would increase the market orientation of the alternative and allow for more flexible implementation; FDA recognition of third parties could be subject to periodic or random audits of their operations and inspections to ensure quality.

Finally, advocates of small firms argue that FDA should provide relief for small producers, who would have difficulty implementing HACCP given their often low profit margin and may be more likely to cease operations due to the near-term transition costs. Small firms already benefit from the general training and technical assistance programmes that FDA is using to ease the transition to HACCP. Additional measures recommended by the U.S. Small Business Administration include exempting very small firms from mandatory HACCP unless the processor has a history of unsafe foods; extending the effective date by another year for small firms to allow for three-year implementation; and creating a generic HACCP plan onto which small firms could sign.⁴ FDA reviewed these alternatives and chose not to adopt them at this time, arguing that agency guidance provided a basic HACCP model and to provide exemptions would place consumers in greater jeopardy of eating adulterated food. FDA did indicate that it would consider a delayed effective date if small firms demonstrated the need for additional time. Accepting the other measures, especially the exemption for very small firms except where problems have been discovered, could significantly reduce costs for small processors and thus require fewer closures while maintaining a focus on the most serious hazards.

NOTES

In addition, the author wishes to thank the following individuals who gave advice and comments during the preparation of this paper: John Morrall and Jonathan Winer of the U.S. Office of Management and Budget; Phillip Spiller of the Food and Drug Administration; and Hans Huigen of the Organisation for Economic Co-operation and Development.

1. Interview with Mary Snyder, FDA Office of Seafood, 30 July 1996.
2. Letter from Senator Frank H. Murkowski, *et al.* to Dr. David Kessler, Commissioner, FDA, 26 July 1995; letter from John R. Cady, President and CEO, National Food Processors Association, to Sally Katzen, Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, 20 October 1995.
3. Review comment from Phillip Spiller, Director, FDA Office of Seafood, 15 August 1996.
4. Letter from Jere Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, to Sally Katzen, 24 October 1995.

OECD PUBLICATIONS, 2, rue André-Pascal, 75775 PARIS CEDEX 16

PRINTED IN FRANCE

(42 97 68 1 P) ISBN 92-64-15567-8 - No. 49635 1996